California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Legislation and Regulation Committee

Greg Lippe, Chair, Public Member
Ramón Castellblanch, Public Member
Randy Kajioka, Professional Member
Amy Gutierrez, Professional Member
Tappan Zee, Public Member

LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee has not met in the past quarter.

PART I LEGISLATION

All section references are to the Business and Professions Code, unless otherwise stated.

a. Enacted Legislation

ATTACHMENT 1

The following Legislation was recently enacted. A copy of each chaptered bill is provided in Attachment 1 and, unless otherwise noted, each is effective on January 1, 2013.

1. <u>SB 1575 (Senate Committee on Business, Professions and Economic Development) Omnibus Provisions – Chapter 799, Statutes of 2012</u>

The Governor signed SB 1575 on September 29, which contained two board-sponsored proposals. These provisions go into effect on January 1, 2013.

- Amends Section 4209 to provide the board with the authority to accept intern hours earned in another state, as specified, and to specify requirements for certifications of intern hours earned for pharmacist applicants.

- Adds Section 4300.1 to ensure the board can put discipline on record even if the license is cancelled.

2. <u>AB 377 (Solorio) Hospital Central Packing Pharmacy – Chapter 687, Statutes of 2012</u>

The Governor signed AB 377 on September 28. The board supported this measure which adds Section 4128 and authorizes the board to issue a specialty license to a

hospital pharmacy. Such a license will authorize a hospital chain under common ownership to prepare consolidated packaging operations to prepare single (unit-) does medications that are bar coded. The unit-dose medications would be delivered to any of multiple campuses of the general acute care hospitals under the same ownership for patient administration. These bar coded medications will also aid hospitals in improving patient safety and in reducing medication errors. Reading a medication's bar code at the patient's bedside prior to administration will help ensure that the right drug is being administered to the right patient at the right time.

The board is developing the license application and processes for this specialty license and intends to have the application available for the next Licensing Committee scheduled for December 11, 2012.

3. AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products – Chapter 75, Statutes of 2012

AB 389 was signed by the Governor in July 2012 and establishes in the Health and Safety Code (commencing with Section 125286.10) the "Standards of Service for Providers of Blood Clotting Products for Home Use Act" ("Act") and requires the Board of Pharmacy to administer and enforce the provisions of the Act. The board had a position of "Oppose" on this legislation, which specifies that "providers of blood clotting products" include hospital pharmacies, health system pharmacies, pharmacies affiliated with hemophilia treatment centers, specialty home care pharmacies and retail pharmacies.

4. AB 1442 (Wieckowski) Common Carriers Transporting Pharmaceutical Waste – Chapter 689, Statutes of 2012

The Governor signed AB 1442 on September 28, 2012. This bill amends the Medical Waste Management Act ("Act" - commencing with Health and Safety Code section 117637) to define, for purposes of the Act, "pharmaceutical waste" and "common carrier"; to provide for a pharmaceutical waste hauling exemption; to allow the use of common carriers to transport pharmaceutical waste for disposal, and to specify what information must be maintained regarding the disposal and transporting of pharmaceutical waste. The Act is under the jurisdiction of the California Department of Public Health. The board was neutral on this measure.

5. AB 1588 (Atkins) Reservist Licensees: Fees and Continuing Education – Chapter 742, Statutes of 2012

The Governor approved this measure on September 29, 2012. The board supported AB 1588 which adds section 114.3 to specify conditions under which the board may waive renewal fees, continuing education requirements and other renewal requirements for a licensee that is called to active duty. It also specifies a license may be placed on "Active Military" – this status is not currently specified in the board's licensing system. Because this measure applies to all boards and bureaus at the Department of Consumer Affairs, the board is working with the department to

determine how it will implement the necessary system changes to reflect the requirements of the bill.

6. AB 1904 (Block) Military Spouses: Expedited Licensure – Chapter 399, Statutes of 2012

The Governor approved AB 1904 on September 20, 2012. This bill requires a board within the Department of Consumer Affairs to expedite the license process for an applicant who holds a license in another state, as specified, and who supplies evidence satisfactory to the board that he or she is married to, or in a domestic partnership or other legal union with an active duty member of the Armed Forces. The bill does not waive any licensing requirements. AB 1904 also authorizes the board to adopt regulations to administer the section. The board supported this legislation.

7. AB 1896 (Chesbro) Tribal Health Programs: Health Care Practitioners – Chapter 119, Statutes of 2012

AB 1896 adds section 719 which applies to all health care boards in the Department of Consumer Affairs. The bill provides that a health care practitioner licensed in any other state and who is employed by a tribal health program, as specified, is exempt from California licensing requirements where that health care practitioner performs services for the tribal health program.

8. AB 2570 (Hill) Licensees: Settlement Agreements – Chapter 561, Statutes of 2012

This bill prohibits a licensee who is regulated by the Department of Consumer Affairs or various boards, as specified, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board.

The bill also prohibits a board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil action to pay additional moneys to the benefit of any plaintiff in the civil action.

9. SB 71 (Leno) Board of Pharmacy Reports – Chapter 728, Statutes of 2012

SB 71 eliminates the requirement that certain state agencies submit certain reports to the Legislature and other agencies on a variety of subjects. This bill deleted the board's requirement to submit to the Legislature by January 1, 2013, the status of the implementation of the prescription drug label requirements required by section 4076.5(f). Only pages relevant to the board's provisions are provided in **Attachment 1**. The board did not have a position on this legislation.

10. SB 1095 (Rubio) Licensing: Clinics – Chapter 454, Statutes of 2012

SB 1095 amends Pharmacy Law to expand the definition of a clinic (§ 4190) to include clinics that are (1) licensed by the CDPH pursuant to section 1204 of the Health and Safety Code, (2) an outpatient setting accredited by an accreditation agency per Section 1248 of the Health and Safety Code, or (3) a Medicare certified ambulatory surgical center. Board licensure is optional. The legislation provides that a clinic licensed by the board may purchase drugs at wholesale, as specified.

The board is modifying the existing clinic application and is updating instructions for applicants. Staff intends to have the clinic application available at the Licensing Committee meeting schedule for December 11, 2012.

11. SB 1099 (Wright) Regulations: Quarterly Effective Dates – Chapter 295, Statutes of 2012

The Administrative Procedure Act specifies requirements for the promulgation of regulations. Currently, and in general, when a regulatory action is adopted or repealed by the board and is subsequently approved by the Office of Administrative Law (OAL), the OAL files the action with the Secretary of State and, with certain exceptions, the regulation is effective 30 days after the date it is filed with the Secretary of State. This bill requires, instead, that the effective date of a regulation shall be effective on a quarterly basis, as follows:

- *January 1, if the regulation is filed with the SOS on September 1 – November 30*
- *April 1, if the regulation is filed with the SOS on December 1 – February 29*
- *July 1, if the regulation is filed with SOS on March 1 – May 31, and*
- *October 1, if the regulation is filed with SOS on June 1 to August 31*

An agency may specify a later effective date, and an agency can request an earlier effective date if the agency makes a written request demonstrating cause for the earlier date.

12. SB 1236 (Price Board of Pharmacy: Sunset – Chapter 332, Statutes of 2012

SB 1236 extends the "sunset" of the Board of Pharmacy to January 2017. The board provided it's "Sunset Review Report 2011" to the Senate Committee on Business, Professions and Economic Development in November 2011 and in March 2012, Board President Stan Weisser and Executive Officer Giny Herold appeared before the committee to respond to the committee's questions.

13. **SB 1301 (Hernandez) Prescription Drugs: 90-Day Supply – Chapter 455, Statutes of 2012**

SB 1301 added section 4064.5 to permit a pharmacist to dispense a 90-day supply of a dangerous drug, so long as specified requirements are met, and provided the prescriber did not indicate "no change to quantity." The section does not apply to controlled substances or to psychotropic drugs. The board supported this measure.

14. **SB 1329 (Simitian) Prescription Drug Collection and Redistribution Program – Chapter 709, Statutes of 2012**

SB 1329 amends the Health and Safety Code (starting at section 150200) to significantly broaden the Surplus Medication Collection and Distribution program. Currently, the law narrowly prescribes those that can donate unused medications, and those to whom the medication can be dispensed. Board staff is concerned that the overly broad amendments could very well compromise the pharmaceutical supply available to all Californians. The board requested that the Governor veto the measure; however, the Governor signed the legislation on September 28. The board's letter to the Governor asking for a veto is provided in **Attachment 1.**

15. **SB 1481 (Negrete-McLeod) Clinical Laboratories: Community Pharmacies – Chapter 874, Statutes of 2012**

SB 1481 adds section 1206.6 and amends other related sections to allow a community pharmacy to perform only specified tests that are classified as waived under CLIA and that are approved by the FDA for over-the-counter sale to the public, provided the pharmacy obtains a valid CLIA certificate of waiver, obtains a registration from the CDPH, and provided that only a pharmacist performs the tests authorized, as specified. The board supported this measure.

b. Legislation Not Enacted

ATTACHMENT 2

The following measures were not enacted in the 2011-2012 Legislative Session. A copy of the latest version of each bill is provided in **Attachment 2.**

1. **SB 419** (Simitian) Solid Waste: Home Generated Sharps
   The Governor vetoed Senator Simitian's bill that would have required a pharmaceutical manufacturer to submit an already required report electronically to the Department of Resources, Recycling and Recovery and also to post the report on its web site.

2. **SB 616** (DeSaulnier) CURES Program
   This measure died in committee. Staff believes the CURES fund will be solvent this fiscal year, but a permanent solution needs to be identified to sustain this valuable system.

c. 2013 Legislative Proposals for Consideration

ATTACHMENT 3

A copy of staff's draft text of each proposal is provided in **Attachment 3.**

1. Addition of Business and Professions Code Section 4008.5 – Requirement to Provide Arrest and Court Documents as Requested by the Board

The board frequently has problems obtaining documents from local or state agencies for the purpose of completing an applicant or licensee investigation; these agencies cite the board's lack of authority to receive these documents. Staff is proposing an amendment to section 4008.5 to provide for the board's explicit authority to receive certified records for this purpose.

2. Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative

Existing law specifies the requirements that must be satisfied for an applicant who applies for a designated representative license. One of those requirements is to have one year paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices, or meet other specified requirements. Pharmacy law does not specify the practice setting or types of facilities in which this one year of paid work experience must be satisfied. Staff is proposing an amendment to section 4053 to clearly specify that the one year of paid work experience shall be earned in a licensed facility, as specified.

3. Amendment to Business and Professions Code Sections 4127.1 and 4127.2 – Sterile Injectable Compounding Pharmacy Requirements

The board's public protection mandate specifies that protection of the public shall be the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions. The board's proposal would amend section 4127.1 to require a pharmacy that is licensed by the board to compound sterile injectable drug products in this state to notify the board when it issues a recall for a sterile injectable drug product, as specified.

Also, To provide for protection of the public, the board believes it is necessary to enhance the licensing and reporting requirements of nonresident pharmacies that are licensed by the board to compound sterile injectable drug products and who ship these products into or dispense these products to Californians. Requiring accreditation, as specified, will ensure the pharmacy has necessary standards and practices in place. Requiring the nonresident pharmacy to complete the board's Compounding Self-Assessment prior to licensure and prior to renewal will assist the pharmacy to ensure it is compliant with California's laws and regulations related to the compounding of drug products. Requiring the pharmacy to provide the board, within specified timeframes, recalls issued for sterile injectable drug products and disciplinary actions or suspension of accreditation will assist the board in the effective enforcement and application of Pharmacy Law.

4. Proposal to Clarify Authorized Acquisition Sources of Dangerous Drugs by Pharmacies

There is no proposal to bring forward at this time.

5. Other Legislative Proposals

Board staff will provide copies of any additional proposals at the Board Meeting.

Senate Bill No. 1575

CHAPTER 799

An act to amend Sections 1640, 1715.5, 1934, 1950.5, 2021, 2064, 2184, 2220, 2424, 2516, 2518, 2570.13, 2904.5, 3057.5, 3742, 3750, 3750.5, 4209, 4980.04, 4980.34, 4980.397, 4980.398, 4980.399, 4980.40, 4980.43, 4980.44, 4980.48, 4980.50, 4980.78, 4980.80, 4984.01, 4984.4, 4984.7, 4984.72, 4989.16, 4989.42, 4992.05, 4992.07, 4992.09, 4992.1, 4996.1, 4996.3, 4996.4, 4996.6, 4996.28, 4999.22, 4999.32, 4999.45, 4999.46, 4999.50, 4999.52, 4999.53, 4999.55, 4999.57, 4999.58, 4999.59, 4999.62, 4999.63, 4999.64, 4999.76, 4999.90, 4999.100, 4999.106, and 4999.120 of, to add Sections 719, 1902.2, 1958.1, and 4300.1 to, and to repeal Section 1909.5 of, the Business and Professions Code, relating to professions and vocations.

[Approved by Governor September 29, 2012. Filed with Secretary of State September 29, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1575, Committee on Business, Professions and Economic Development. Professions and vocations.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs.

(1) Under existing federal law, licensed health professionals employed by a tribal health program are required to be exempt, if licensed in any state, from the licensing requirements of the state in which the tribal health program performs specified services. A tribal health program is defined as an Indian tribe or tribal organization that operates any health program, service, function, activity, or facility funded, in whole or part, by the Indian Health Service.

Existing law provides for the licensure and regulation of health care practitioners by various healing arts boards within the Department of Consumer Affairs.

This bill would codify that federal requirement by specifying that a person who is licensed as a health care practitioner in any other state and is employed by a tribal health program is exempt from this state's licensing requirements with respect to acts authorized under the person's license where the tribal health program performs specified services.

(2) Existing law, the Dental Practice Act, provides for the licensure and regulation of the practice of dentistry by the Dental Board of California within the Department of Consumer Affairs. Existing law establishes the Dental Hygiene Committee of California under the jurisdiction of the board

and provides for the licensure and regulation of the practice of dental hygienists by the committee.

This bill would require dental hygienists, upon initial licensure and renewal, to report their employment status to the committee and would require that information to be posted on the committee's Internet Web site.

Existing law provides that a dental hygienist may have his or her license suspended or revoked by the board for committing acts of unprofessional conduct, as defined.

This bill would include within the definition of unprofessional conduct the aiding or abetting of the unlicensed or unlawful practice of dental hygiene.

Existing law authorizes the committee to deny an application for licensure or to revoke or suspend a license for specified reasons.

This bill would require the committee to deny a license or renewal of a license to any person who is required by law to register as a sex offender.

Existing law authorizes the Dental Board of California to issue a special permit to persons meeting certain requirements, including furnishing satisfactory evidence of having graduated from a dental college.

This bill would allow that requirement to also be met through completion of an accredited advanced education program.

The bill would delete obsolete references.

(3) Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Under existing law, the board issues a physician and surgeon's certificate to a licensed physician and surgeon. Existing law provides for the licensure and regulation of the practice of podiatric medicine by the California Board of Podiatric Medicine within the Medical Board of California.

Existing law requires the Medical Board of California and the California Board of Podiatric Medicine to provide written notification by certified mail to any physician and surgeon or podiatrist who does not renew his or her license within 60 days of expiration.

This bill would require the Medical Board of California and the California Board of Podiatric Medicine to provide that written notification either by certified mail or by electronic mail if requested by the licensee. The bill would require the Medical Board of California to annually send an electronic notice to all licensees and applicants requesting confirmation that his or her electronic mail address is current.

Existing law authorizes the Medical Board of California to take action against all persons guilty of violating the Medical Practice Act. Existing law requires the Medical Board of California to enforce and administer various disciplinary provisions as to physician and surgeon certificate holders.

This bill would specify that those certificate holders include those who hold certificates that do not permit them to practice medicine, such as, but not limited to, retired, inactive, or disabled status certificate holders.

(4) Existing law, the Licensed Midwifery Practice Act of 1993, provides for the licensure and regulation of the practice of licensed midwifery by the Medical Board of California. A violation of the act is a crime. Under existing law, these licenses are subject to biennial renewal that includes the payment of a specified fee and the completion of specified continuing education.

This bill would exempt a licensee from those renewal requirements if the licensee has applied to the board and has been issued a retired status license. The bill would prohibit the holder of a retired status license from engaging in the practice of midwifery. Because a violation of that prohibition would constitute a crime, the bill would impose a state-mandated local program.

(5) Existing law, the Occupational Therapy Practice Act, requires the California Board of Occupational Therapy to ensure proper supervision of occupational therapy assistants and aides. An aide is required to be supervised by an occupational therapist.

This bill would also provide for an aide to be supervised by an occupational therapy assistant.

(6) Existing law, the Psychology Licensing Law, provides for the licensure and regulation of psychologists by the Board of Psychology. Existing law provides that a licensed psychologist is a health care practitioner for purposes of specified telehealth provisions that concern the delivery of health care via information and communication technologies.

This bill would instead provide that a licensed psychologist is a health care provider subject to those telehealth provisions.

(7) Existing law, the Respiratory Care Practice Act, provides for the licensure and regulation of the practice of respiratory care by the Respiratory Care Board of California.

Under existing law, during the period of any clinical training, a student respiratory care practitioner is required to be under the direct supervision, as defined, of a person holding a valid and current license.

This bill would require such a student to be under the direct supervision of a person with a valid, current, and unrestricted license.

Existing law authorizes the board to order the denial, suspension, or revocation of, or the imposition of probationary conditions upon, a license for specified causes including a pattern of substandard care.

This bill would expand that provision to also include negligence in the licensee's practice as a respiratory care practitioner, or in any capacity as a health care worker, consultant, supervisor, manager or health facility owner, or as a party responsible for the care of another.

Existing law authorizes the board to deny, suspend, place on probation, or revoke the license of any applicant or licenseholder who has obtained, possessed, used, or administered to himself or herself, or furnished or administered to another, any controlled substances or dangerous drug, except as directed by a specified health care provider.

This bill would also make illegally possessing any associated paraphernalia a ground for the denial, suspension, placing on probation, or revocation of a license.

(8) Existing law, the Pharmacy Law, provides for the California State Board of Pharmacy within the Department of Consumer Affairs, to license and regulate the practice of pharmacy.

Existing law authorizes the board to suspend or revoke a license if the holder has been convicted of certain crimes or has engaged in unprofessional conduct, as specified.

This bill would modify the practice requirements applicable to intern pharmacists. The bill would also provide that the board continues to have jurisdiction in a disciplinary action against a licensee, even if the license is expired, canceled, forfeited, suspended, revoked, placed on retired status, or voluntarily surrendered.

(9) Under existing law, the Board of Behavioral Sciences is responsible for the licensure and regulation of marriage and family therapists, licensed educational psychologists, licensed clinical social workers, and licensed professional clinical counselors.

Under existing law, a license that is not renewed within 3 years after its expiration may not be renewed. However, the former licensee is authorized to apply for and obtain a new license if certain requirements are met, including, but not limited to, passing one or more current licensing examinations, as specified and submitting certain fees.

This bill would additionally require a former licensee to comply with the fingerprint requirements established by board regulation or as directed by the board. The bill would make other technical and clarifying changes.

Existing law makes various changes to the licensing and associated examination requirements for marriage and family therapists, clinical social workers, and professional clinical counselors, effective January 1, 2013.

This bill would delay the implementation of these and other related changes until January 1, 2014.

(10) Existing law, the Marriage and Family Therapist Act, with respect to applicants for licensure or registration by reciprocity or for those applicants who obtained education or experience outside of California that apply on and after January 1, 2014, existing law provides that education is substantially equivalent if certain requirements are met, including the completion of a course in California law and professional ethics.

This bill would require that course to be 18 hours in length.

For persons who apply for licensure between January 1, 2010, and December 31, 2013, existing law authorizes the board to issue a license to a person who holds a valid license from another state if certain requirements are met, including the completion of specified coursework or training. Existing law provides that an applicant who completed a specified course in law and professional ethics is required to complete an 18-hour course in California law and professional ethics.

This bill would instead specify that an 18-hour course in California law and professional ethics is only required if the above specified course in law and professional ethics does not meet certain requirements. The bill would make other technical changes to those provisions.

The bill would rename the act as the Licensed Marriage and Family Therapist Act.

(11) Existing law, the Licensed Professional Clinical Counselor Act, provides for the licensure and regulation of the practice of professional clinical counseling by the Board of Behavioral Sciences.

Under existing law, to qualify for registration, an intern applicant is required to meet certain qualifications. With respect to applicants for registration who began graduate study before August 1, 2012, and complete study on or before December 31, 2018, an applicant is required to complete a minimum of 18 contact hours of instruction in California law and professional ethics prior to registration as an intern.

This bill would describe the content of that instruction for professional clinical counselors.

Existing law authorizes the board to refuse to issue any registration or license, or to suspend or revoke the registration or license of any intern or licensed professional clinical counselor, if the applicant, licensee, or registrant has been guilty of unprofessional conduct that includes, but is not limited to, the conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of specified substances, or any combination thereof.

This bill would delete the conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of specified substances, or any combination thereof, from the list of what constitutes professional conduct. The bill would make it unprofessional conduct to willfully violate specified provisions governing patient access to health care records.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would incorporate additional changes to certain provisions proposed by AB 1733, SB 1183, and SB 1527 if one or more of those bills is also enacted and this bill is chaptered last.

The people of the State of California do enact as follows:

SECTION 1. Section 719 is added to the Business and Professions Code, to read:

719. (a) A person who possesses a current, valid license as a health care practitioner in any other state and is employed by a tribal health program, as defined in Section 1603 of Title 25 of the United States Code, shall be exempt from any licensing requirement described in this division with respect to acts authorized under the person's license where the tribal health program performs the services described in the contract or compact of the

tribal health program under the Indian Self-Determination and Education Assistance Act (25 U.S.C. Sec. 450 et seq.).

(b) For purposes of this section, "health care practitioner" means any person who engages in acts that are the subject of licensure or regulation under the law of any other state.

SEC. 2. Section 1640 of the Business and Professions Code is amended to read:

1640. Any person meeting all the following eligibility requirements may apply for a special permit:

(a) Furnishing satisfactory evidence of having a pending contract with a California dental college approved by the board as a full-time professor, an associate professor, or an assistant professor.

(b) Furnishing satisfactory evidence of having graduated from a dental college approved by the board, or of having completed an advanced education program accredited by either the Commission on Dental Accreditation of the American Dental Association or a national accrediting body approved by the board.

(c) Furnishing satisfactory evidence of having been certified as a diplomate of a specialty board or, in lieu thereof, establishing his or her qualifications to take a specialty board examination or furnishing satisfactory evidence of having completed an advanced educational program in a discipline from a dental college approved by the board.

(d) Furnishing satisfactory evidence of successfully completing an examination in California law and ethics developed and administered by the board.

(e) Paying a fee for applications as provided by this chapter.

SEC. 3. Section 1715.5 of the Business and Professions Code is amended to read:

1715.5. (a) A licensee shall, upon his or her initial licensure and any subsequent application for renewal, report the completion of any advanced educational program accredited by the Committee on Dental Accreditation in a dental specialty recognized by the American Dental Association.

(b) The licensee shall also report, upon his or her initial licensure and any subsequent application for renewal, the practice or employment status of the licensee, designated as one of the following:

(1) Full-time practice or employment in a dental practice of 32 hours per week or more in California. This reporting requirement shall also apply to a dental auxiliary licensee.

(2) Full-time practice or employment in a dental practice outside of California.

(3) Part-time practice or employment in a dental practice for less than 32 hours per week in California.

(4) Dental administrative employment that does not include direct patient care, as may further be defined by the board.

(5) Retired.

(6) Other practice or employment status, as may be further defined by the board.

licensed physician and surgeon, dentist, podiatrist, or other authorized health care provider, or illegally possessed any associated paraphernalia.

(b) Used any controlled substance as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or any dangerous drug as defined in Article 2 (commencing with Section 4015) of Chapter 9 of this code, or alcoholic beverages, to an extent or in a manner dangerous or injurious to himself or herself, or to others, or that impaired his or her ability to conduct with safety the practice authorized by his or her license.

(c) Applied for employment or worked in any health care profession or environment while under the influence of alcohol.

(d) Been convicted of a criminal offense involving the consumption or self-administration of any of the substances described in subdivisions (a) and (b), or the possession of, or falsification of a record pertaining to, the substances described in subdivision (a), in which event the record of the conviction is conclusive evidence thereof.

(e) Been committed or confined by a court of competent jurisdiction for intemperate use of or addiction to the use of any of the substances described in subdivisions (a), (b), and (c), in which event the court order of commitment or confinement is prima facie evidence of that commitment or confinement.

(f) Falsified, or made grossly incorrect, grossly inconsistent, or unintelligible entries in any hospital, patient, or other record pertaining to the substances described in subdivision (a).

SEC. 22. Section 4209 of the Business and Professions Code is amended to read:

4209. (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

SEC. 23. Section 4300.1 is added to the Business and Professions Code, to read:

4300.1. The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

SEC. 24. Section 4980.04 of the Business and Professions Code is amended to read:

4980.04. This chapter shall be known and may be cited as the Licensed Marriage and Family Therapist Act.

SEC. 25. Section 4980.34 of the Business and Professions Code is amended to read:

4980.34. It is the intent of the Legislature that the board employ its resources for each and all of the following functions:

(a) The licensing of marriage and family therapists, clinical social workers, professional clinical counselors, and educational psychologists.

(b) The development and administration of licensing examinations and examination procedures, as specified, consistent with prevailing standards for the validation and use of licensing and certification tests. Examinations shall measure knowledge and abilities demonstrably important to the safe, effective practice of the profession.

(c) Enforcement of laws designed to protect the public from incompetent, unethical, or unprofessional practitioners.

(d) Consumer education.

SEC. 26. Section 4980.397 of the Business and Professions Code is amended to read:

4980.397. (a) Effective January 1, 2014, an applicant for licensure as a marriage and family therapist shall pass the following two examinations as prescribed by the board:

(1) A California law and ethics examination.

(2) A clinical examination.

(b) Upon registration with the board, a marriage and family therapist intern shall, within the first year of registration, take an examination on California law and ethics.

(c) A registrant may take the clinical examination only upon meeting all of the following requirements:

(1) Completion of all required supervised work experience.

(2) Completion of all education requirements.

(3) Passage of the California law and ethics examination.

(d) This section shall become operative on January 1, 2014.

SEC. 27. Section 4980.398 of the Business and Professions Code is amended to read:

4980.398. (a) Each applicant who had previously taken and passed the standard written examination but had not passed the clinical vignette examination shall also obtain a passing score on the clinical examination in order to be eligible for licensure.

Assembly Bill No. 377

CHAPTER 687

An act to amend Section 4029 of, and to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

[Approved by Governor September 28, 2012. Filed with Secretary of State September 28, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 377, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant.

This bill would authorize a centralized hospital packaging pharmacy to prepare medications, by performing specified functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership, as defined, and within a 75-mile radius of each other. The bill would require a centralized hospital packaging pharmacy to obtain a specialty license from the board, and the bill would make these licenses subject to annual renewal. The bill would condition both the issuance and renewal of a specialty license on a board inspection of the centralized hospital packaging pharmacy to ensure that the pharmacy is in compliance with the bill's provisions and regulations established by the board. The bill would impose specified issuance and annual renewal fees for a specialty license, and because these fees would be deposited into the Pharmacy Board Contingent Fund, a continuously appropriated fund, the bill would make an appropriation.

The bill would authorize a centralized hospital packaging pharmacy to prepare and store a limited quantity of specified unit dose drugs in advance of receipt of a patient-specific prescription in a specified quantity. The bill would impose various requirements on centralized hospital packaging pharmacies, including, but not limited to, that medications be barcoded to be readable at the inpatient's bedside and that medication labels contain

specified information. The bill would make these pharmacies and pharmacists responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the packaging pharmacy. Because a knowing violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4029 of the Business and Professions Code is amended to read:

4029. (a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a pharmacy that may be located outside of the hospital in another physical plant that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. Centralized Hospital Packaging Pharmacies

4128. (a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.

(2) Preparing compounded unit dose drugs for parenteral therapy for administration to inpatients, if each compounded unit dose drug is barcoded to contain at least the information required by Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.

(b) For purposes of this article, "common ownership" means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

4128.2. (a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

(h) The fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars ($600) and may be increased by the board to eight hundred dollars ($800).

4128.3. A centralized hospital packaging pharmacy may prepare and store a limited quantity of the unit dose drugs authorized by Section 4128 in advance of receipt of a patient-specific prescription in a quantity as is necessary to ensure continuity of care for an identified population of inpatients of the general acute care hospital based on a documented history of prescriptions for that patient population.

4128.4. Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside. Upon reading the barcode, the following information shall be retrievable:

(a) The date the medication was prepared.
(b) The components used in the drug product.
(c) The lot number or control number.
(d) The expiration date.
(e) The National Drug Code Directory number.
(f) The name of the centralized hospital packaging pharmacy.

4128.5. The label for each unit dose medication produced by a centralized hospital packaging pharmacy shall contain all of the following:
(a) The expiration date.
(b) The established name of the drug.
(c) The quantity of the active ingredient.
(d) Special storage or handling requirements.

4128.6. All compounding and packaging functions specified in Section 4128 shall be performed only in the licensed centralized hospital packaging pharmacy and that pharmacy shall comply with all applicable federal and state statutes and regulations, including, but not limited to, regulations regarding compounding and, when appropriate, sterile injectable compounding.

4128.7. A centralized hospital packaging pharmacy and the pharmacists working in the pharmacy shall be responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Assembly Bill No. 389

CHAPTER 75

An act to add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic diseases.

[Approved by Governor July 10, 2012. Filed with Secretary of State July 10, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 389, Mitchell. Bleeding disorders.

Existing law, the Holden-Moscone-Garamendi Genetically Handicapped Person's Program, requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

This bill would impose specified requirements on providers of blood clotting products for home use, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce these provisions.

The people of the State of California do enact as follows:

SECTION 1. Article 5 (commencing with Section 125286.10) is added to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, to read:

Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act

125286.10. This article shall be known, and may be cited, as the Standards of Service for Providers of Blood Clotting Products for Home Use Act.

125286.15. The Legislature hereby finds and declares all of the following:

(a) Hemophilia is a rare, hereditary, bleeding disorder affecting at least 4,000 persons in California and is a chronic, lifelong, and incurable, but treatable, disease.

(b) Von Willebrand disease is a human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand factor in human blood, which is a protein that helps clot blood. Von Willebrand disease is

a chronic, lifelong, incurable, but treatable, disease affecting at least 360,000 Californians.

(c) Until the 1970s, people with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a shortened lifespan. More recently, the production of highly purified blood clotting factors has provided people with hemophilia and other bleeding disorders the opportunity to lead normal lives, free of pain and crippling arthritis.

(d) The preferred method of treatment of hemophilia today is intravenous injection, or infusion, of prescription blood clotting products several times per week, along with case management and specialized medical care at a federally designated regional hemophilia treatment center.

(e) Pharmacies and other entities specializing in the delivery of blood clotting products and related equipment, supplies, and services for home use form a growing enterprise in California.

(f) Timely access to federally designated regional hemophilia centers and appropriate products and services in the home, including infusion of blood clotting products and related equipment, and supplies and services for persons with hemophilia and other bleeding disorders, reduces mortality and bleeding-related hospitalizations according to the federal Centers for Disease Control and Prevention and the Medical and Scientific Advisory Council of the National Hemophilia Foundation.

(g) Eligible persons with hemophilia or other bleeding disorders may receive treatment through the Genetically Handicapped Persons Program, the California Children's Services Program, and the Medi-Cal program.

(h) For the benefit of persons with hemophilia or other bleeding disorders, the purposes of this article are to do the following:

(1) Establish standards of service for entities that deliver blood clotting products and related equipment, supplies, and services for home use.

(2) Promote access to a full range of essential, cost-effective, lifesaving, blood clotting products and related equipment, supplies, and high-quality services for home use for persons with hemophilia and other bleeding disorders.

125286.20. Unless the context otherwise requires, the following definitions shall apply for purposes of this article:

(a) "Assay" means the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug.

(b) "Ancillary infusion equipment and supplies" means the equipment and supplies required to infuse a blood clotting product into a human vein, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs.

(c) "Bleeding disorder" means a medical condition characterized by a deficiency or absence of one or more essential blood clotting proteins in the human blood, often called "factors," including all forms of hemophilia and other bleeding disorders that, without treatment, result in uncontrollable bleeding or abnormal blood clotting.

(d) "Blood clotting product" means an intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, factor VII, factor VIIa, factor VIII, and factor IX products, von Willebrand factor products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

(e) "Emergency" means care as defined in Section 1317.1.

(f) "Hemophilia" means a human bleeding disorder caused by a hereditary deficiency of the factors I, II, V, VIII, IX, XI, XII, or XIII blood clotting protein in human blood.

(g) "Hemophilia treatment center" means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding specifically for the treatment of patients with bleeding disorders from federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.

(h) "Home use" means infusion or other use of a blood clotting product in a place other than a state-recognized hemophilia treatment center or other clinical setting. Places where home use occurs include, without limitation, a home or other nonclinical setting.

(i) "Patient" means a person needing a blood clotting product for home use.

(j) (1) "Provider of blood clotting products for home use" means all the following pharmacies, except as described in Section 125286.35, that dispense blood clotting factors for home use:

(A) Hospital pharmacies.

(B) Health system pharmacies.

(C) Pharmacies affiliated with hemophilia treatment centers.

(D) Specialty home care pharmacies.

(E) Retail pharmacies.

(2) The providers described in this subdivision shall include a health care service plan and all its affiliated providers if the health care service plan exclusively contracts with a single medical group in a specified geographic area to provide professional services to its enrollees.

125286.25. Each provider of blood clotting products for home use shall meet all of the following requirements:

(a) Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient and the medical and psychosocial management thereof, including, but not limited to, home therapy.

(b) Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors.

(c) Maintain 24-hour on-call service seven days a week for every day of the year, adequately screen telephone calls for emergencies, acknowledge all telephone calls within one hour or less, and have access to knowledgeable pharmacy staffing on call 24 hours a day, to initiate emergency requests for clotting factors.

(d) Have the ability to obtain all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges (low, medium, and high, as applicable) and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained.

(e) Supply all necessary ancillary infusion equipment and supplies with each prescription, as needed.

(f) Store and ship, or otherwise deliver, all blood clotting products in conformity with all state and federally mandated standards, including, but not limited to, the standards set forth in the product's approved package insert (PI).

(g) Upon receiving approved authorization for a nonemergency prescription, provided manufacturer supply exists, ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less for established and new patients.

(h) Upon receiving approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, deliver prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport.

(i) Provide patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery and respond to these calls within a reasonable time period.

(j) Provide patients with notification of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of the provider of blood clotting products for home use receiving notification and participate in the National Patient Notification System for blood clotting product recalls.

(k) Provide language interpretive services over the telephone or in person, as needed by the patient.

(*l*) Have a detailed plan for meeting the requirements of this article in the event of a natural or manmade disaster or other disruption of normal business operations.

(m) Provide appropriate and necessary recordkeeping and documentation as required by state and federal law and retain copies of the patient's prescriptions.

(n) Comply with the privacy and confidentiality requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

125286.30. The California State Board of Pharmacy shall administer and enforce this article.

125286.35. Nothing in this article shall apply to either hospital pharmacies or health system pharmacies that dispense blood clotting products due only to emergency, urgent care, or inpatient encounters, or if an inpatient is discharged with a supply of blood clotting products for home use.

O

Assembly Bill No. 1442

CHAPTER 689

An act to amend Sections 117935, 117945, 117960, 118000, 118040, and 118165 of, and to add Sections 117637, 117748, 118032, and 118033 to, the Health and Safety Code, relating to pharmaceutical waste.

[Approved by Governor September 28, 2012. Filed with Secretary of State September 28, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1442, Wieckowski. Pharmaceutical waste.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Existing law requires that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. Violation of these provisions of law is a crime.

This bill would define pharmaceutical waste for purposes of the Medical Waste Management Act, and would exempt a pharmaceutical waste generator or parent organization that employs health care professionals who generate pharmaceutical waste from specified medical waste hauling requirements if the generator, health care professional, or parent organization retains specified documentation and meets specified requirements and if the facility receiving the medical waste retains specified documentation and meets specified requirements. The bill would authorize pharmaceutical waste to be transported by the generator or health care professional who generated the pharmaceutical waste, a staff member of the generator or health care professional, or common carrier, as defined, pursuant to these provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 117637 is added to the Health and Safety Code, to read:

117637. "Common carrier" means either of the following:

(a) A person or company that has a United States Department of Transportation number issued by the Federal Motor Carrier Safety Administration and is registered with the Federal Motor Carrier Safety Administration as a for-hire property carrier.

(b) A person or company that has a motor carrier of property permit issued by the Department of Motor Vehicles pursuant to the Motor Carriers of Property Permit Act (Division 14.85 (commencing with Section 34600) of the Vehicle Code) and, if applicable, a carrier identification number issued by the Department of the California Highway Patrol pursuant to Section 34507.5 of the Vehicle Code.

SEC. 2. Section 117748 is added to the Health and Safety Code, to read:

117748. (a) "Pharmaceutical waste" means any pharmaceutical, as defined in Section 117747, that is a waste, as defined in Section 25124.

(b) For purposes of this part, "pharmaceutical waste" does not include any pharmaceutical that meets either of the following criteria:

(1) The pharmaceutical is being sent out of the State of California to a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4161 of the Business and Professions Code.

(2) The pharmaceutical is being sent by a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, offsite for treatment and disposal in accordance with applicable laws, or to a reverse distributor that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4160 of the Business and Professions Code and as a permitted transfer station if the reverse distributor is located within the State of California.

SEC. 3. Section 117935 of the Health and Safety Code is amended to read:

117935. Any small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite.

(f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, the name of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment and disposal, and, if applicable, the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal pursuant to Section 118032.

(g) A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable.

(h) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable.

(i) A statement certifying that the information provided is complete and accurate.

SEC. 4. Section 117945 of the Health and Safety Code is amended to read:

117945. Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

(a) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.

(b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030, and, if applicable, the name of the common carrier transporting pharmaceutical waste pursuant to Section 118032. The small quantity generator shall maintain these records for not less than two years.

SEC. 5. Section 117960 of the Health and Safety Code is amended to read:

117960. Any large quantity generator required to register with the enforcement agency pursuant to Section 117950 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, including incinerators or steam sterilizers or other treatment facilities as determined by the enforcement agency, the treatment capacity of the onsite treatment facility.

(f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable, and, if applicable, the name and business address of the common carrier transporting pharmaceutical waste pursuant to Section 118032.

(g) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building

tenants may subscribe or are required by the building management to subscribe, if applicable.

(h) The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable.

(i) An emergency action plan complying with regulations adopted by the department.

(j) A statement certifying that the information provided is complete and accurate.

SEC. 6. Section 118000 of the Health and Safety Code is amended to read:

118000. (a) Except as otherwise exempted pursuant to Section 118030 or 118032, all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118025) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate, upon demand, to any enforcement agency personnel or authorized employee of the Department of the California Highway Patrol.

(b) Except for small quantity generators transporting medical waste pursuant to Section 118030 or small quantity generators or common carriers transporting pharmaceutical waste pursuant to Section 118032, medical waste shall be transported to a permitted offsite medical waste treatment facility or a permitted transfer station in leak-resistant and fully enclosed rigid secondary containers that are then loaded into an enclosed cargo body.

(c) A person shall not transport medical waste in the same vehicle with other waste unless the medical waste is separately contained in rigid containers or kept separate by barriers from other waste, or unless all of the waste is to be handled as medical waste in accordance with this part.

(d) Medical waste shall only be transported to a permitted medical waste treatment facility, or to a transfer station or another registered generator for the purpose of consolidation before treatment and disposal, pursuant to this part.

(e) Facilities for the transfer of medical waste shall be annually inspected and issued permits in accordance with the regulations adopted pursuant to this part.

(f) Any persons manually loading or unloading containers of medical waste shall be provided by their employer at the beginning of each shift with, and shall be required to wear, clean and protective gloves and coveralls, changeable lab coats, or other protective clothing. The department may require, by regulation, other protective devices appropriate to the type of medical waste being handled.

SEC. 7. Section 118032 is added to the Health and Safety Code, to read:

118032. A pharmaceutical waste generator or parent organization that employs health care professionals who generate pharmaceutical waste is exempt from the requirements of subdivision (a) of Section 118000 if all of the following requirements are met:

(a) The generator or parent organization has on file one of the following:

(1) If the generator or parent organization is a small quantity generator required to register pursuant to Chapter 4 (commencing with Section 117915), a medical waste management plan prepared pursuant to Section 117935.

(2) If the generator or parent organization is a small quantity generator not required to register pursuant to Chapter 4 (commencing with Section 117915), the information document maintained pursuant to subdivision (a) of Section 117945.

(3) If the generator or parent organization is a large quantity generator, a medical waste management plan prepared pursuant to Section 117960.

(b) The generator or health care professional who generated the pharmaceutical waste transports the pharmaceutical waste himself or herself, or directs a member of his or her staff to transport the pharmaceutical waste to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal, or contracts with a common carrier to transport the pharmaceutical waste to a permitted medical waste treatment facility or transfer station.

(c) Except as provided in subdivision (d), all of the following requirements are met:

(1) Prior to shipment of the pharmaceutical waste, the generator notifies the intended destination facility that it is shipping pharmaceutical waste to it and provides a copy of the tracking document, as specified in Section 118040.

(2) The generator and the facility receiving the pharmaceutical waste maintain the tracking document, as specified in Section 118040.

(3) The facility receiving the pharmaceutical waste notifies the generator of the receipt of the pharmaceutical waste shipment and any discrepancies between the items received and the tracking document, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(4) The generator notifies the enforcement agency of any discrepancies between the items received and the tracking document, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(d) (1) Notwithstanding subdivision (c), if a health care professional who generates pharmaceutical waste returns the pharmaceutical waste to the parent organization for the purpose of consolidation before treatment and disposal over a period of time, a single-page form or multiple entry log may be substituted for the tracking document, if the form or log contains all of the following information:

(A) The name of the person transporting the pharmaceutical waste.

(B) The number of containers of pharmaceutical waste. This clause does not require any generator to maintain a separate pharmaceutical waste

container for every patient or to maintain records as to the specified source of the pharmaceutical waste in any container.

(C) The date that the pharmaceutical waste was returned.

(2) The form or log described in paragraph (1) shall be maintained in the files of the health care professional who generates the pharmaceutical waste and the parent organization or another health care facility that receives the pharmaceutical waste.

(3) This subdivision does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility, provided the form or log meets the requirements specified in paragraphs (1) and (2).

SEC. 8. Section 118033 is added to the Health and Safety Code, to read:

118033. The pharmaceutical waste that is separated from medical waste by the generator shall be maintained in a manner to secure the pharmaceutical waste contents from access by unauthorized individuals. Any suspected or confirmed tampering of, unauthorized access to, or loss of this pharmaceutical waste shall be reported to the appropriate state licensing authority.

SEC. 9. Section 118040 of the Health and Safety Code is amended to read:

118040. (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 118030.

(2) The type of medical waste transported and the quantity or aggregate weight of medical waste transported.

(3) The name, address, and telephone number of the generator.

(4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.

(5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer

station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.

(c) Any hazardous waste transporter or generator transporting medical waste in a vehicle shall have a tracking document in his or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information concerning the medical waste that the enforcement agency may require.

(d) A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original tracking document.

(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

(f) Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the medical waste is crossing an international border, the medical waste shall be treated in accordance with Chapter 8 (commencing with Section 118215) prior to being transported out of the state.

SEC. 10. Section 118165 of the Health and Safety Code is amended to read:

118165. On and after April 1, 1991, all persons operating a medical waste treatment facility shall maintain individual records for a period of three years and shall report or submit to the enforcement agency upon request, all of the following information:

(a) The type of treatment facility and its capacity.

(b) All treatment facility operating records.

(c) Copies of the tracking documents for all medical waste it receives for treatment from offsite generators, hazardous waste haulers, or, pursuant to Section 118032, common carriers.

SEC. 11. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Assembly Bill No. 1588

CHAPTER 742

An act to add Section 114.3 to the Business and Professions Code, relating to professions and vocations.

[Approved by Governor September 29, 2012. Filed with Secretary of State September 29, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1588, Atkins. Professions and vocations: reservist licensees: fees and continuing education.

Existing law provides for the regulation of various professions and vocations by boards within the Department of Consumer Affairs and for the licensure or registration of individuals in that regard. Existing law authorizes any licensee whose license expired while he or she was on active duty as a member of the California National Guard or the United States Armed Forces to reinstate his or her license without examination or penalty if certain requirements are met.

This bill would require the boards described above, with certain exceptions, to waive the renewal fees, continuing education requirements, and other renewal requirements as determined by the board, if any are applicable, of any licensee or registrant who is called to active duty as a member of the United States Armed Forces or the California National Guard if certain requirements are met. The bill would, except as specified, prohibit a licensee or registrant from engaging in any activities requiring a license while a waiver is in effect. The bill would require a licensee or registrant to meet certain renewal requirements within a specified time period after being discharged from active duty service prior to engaging in any activity requiring a license. The bill would require a licensee or registrant to notify the board of his or her discharge from active duty within a specified time period.

The people of the State of California do enact as follows:

SECTION 1. Section 114.3 is added to the Business and Professions Code, to read:

114.3. (a) Notwithstanding any other provision of law, every board, as defined in Section 22, within the department shall waive the renewal fees, continuing education requirements, and other renewal requirements as determined by the board, if any are applicable, for any licensee or registrant called to active duty as a member of the United States Armed Forces or the California National Guard if all of the following requirements are met:

(1) The licensee or registrant possessed a current and valid license with the board at the time he or she was called to active duty.

(2) The renewal requirements are waived only for the period during which the licensee or registrant is on active duty service.

(3) Written documentation that substantiates the licensee or registrant's active duty service is provided to the board.

(b) (1) Except as specified in paragraph (2), the licensee or registrant shall not engage in any activities requiring a license during the period that the waivers provided by this section are in effect.

(2) If the licensee or registrant will provide services for which he or she is licensed while on active duty, the board shall convert the license status to military active and no private practice of any type shall be permitted.

(c) In order to engage in any activities for which he or she is licensed once discharged from active duty, the licensee or registrant shall meet all necessary renewal requirements as determined by the board within six months from the licensee's or registrant's date of discharge from active duty service.

(d) After a licensee or registrant receives notice of his or her discharge date, the licensee or registrant shall notify the board of his or her discharge from active duty within 60 days of receiving his or her notice of discharge.

(e) A board may adopt regulations to carry out the provisions of this section.

(f) This section shall not apply to any board that has a similar license renewal waiver process statutorily authorized for that board.

O

Assembly Bill No. 1904

CHAPTER 399

An act to add Section 115.5 to the Business and Professions Code, relating to professions and vocations.

[Approved by Governor September 20, 2012. Filed with Secretary of State September 20, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1904, Block. Professions and vocations: military spouses: expedited licensure.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law provides for the issuance of reciprocal licenses in certain fields where the applicant, among other requirements, has a license to practice within that field in another jurisdiction, as specified. Existing law authorizes a licensee to reinstate an expired license without examination or penalty if, among other requirements, the license expired while the licensee was on active duty as a member of the California National Guard or the United States Armed Forces.

This bill would require a board within the department to expedite the licensure process for an applicant who holds a license in the same profession or vocation in another jurisdiction and is married to, or in a legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders.

The people of the State of California do enact as follows:

SECTION 1. Section 115.5 is added to the Business and Professions Code, to read:

115.5. (a) A board within the department shall expedite the licensure process for an applicant who meets both of the following requirements:

(1) Supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.

(2) Holds a current license in another state, district, or territory of the United States in the profession or vocation for which he or she seeks a license from the board.

(b) A board may adopt regulations necessary to administer this section.

O

Assembly Bill No. 1896

CHAPTER 119

An act to amend the heading of Article 10 (commencing with Section 710) of Chapter 1 of Division 2 of, and to add Section 719 to, the Business and Professions Code, relating to healing arts.

[Approved by Governor July 13, 2012. Filed with Secretary of State July 13, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1896, Chesbro. Tribal health programs: health care practitioners.

Under existing federal law, licensed health professionals employed by a tribal health program are required to be exempt, if licensed in any state, from the licensing requirements of the state in which the tribal health program performs specified services. A tribal health program is defined as an Indian tribe or tribal organization that operates any health program, service, function, activity, or facility funded, in whole or part, by the Indian Health Service.

Existing law provides for the licensure and regulation of health care practitioners by various healing arts boards within the Department of Consumer Affairs.

This bill would codify that federal requirement by specifying that a person who is licensed as a health care practitioner in any other state and is employed by a tribal health program is exempt from this state's licensing requirements with respect to acts authorized under the person's license where the tribal health program performs specified services.

The people of the State of California do enact as follows:

SECTION 1. The heading of Article 10 (commencing with Section 710) of Chapter 1 of Division 2 of the Business and Professions Code is amended to read:

Article 10. Federal Personnel and Tribal Health Programs

SEC. 2. Section 719 is added to the Business and Professions Code, to read:

719. (a) A person who is licensed as a health care practitioner in any other state and is employed by a tribal health program, as defined in Section 1603 of Title 25 of the United States Code, shall be exempt from any licensing requirement described in this division with respect to acts authorized under the person's license where the tribal health program

performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act (25 U.S.C. Sec. 450 et seq.).

(b) For purposes of this section, “health care practitioner” means any person who engages in acts that are the subject of licensure or regulation under the law of any other state.

O

Assembly Bill No. 2570

CHAPTER 561

An act to add Section 143.5 to the Business and Professions Code, relating to professions and vocations.

[Approved by Governor September 25, 2012. Filed with Secretary of State September 25, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2570, Hill. Licensees: settlement agreements.

Existing law provides that it is a cause for suspension, disbarment, or other discipline for an attorney to agree or seek agreement that the professional misconduct or the terms of a settlement of a claim for professional misconduct are not to be reported to the disciplinary agency, or to agree or seek agreement that the plaintiff shall withdraw a disciplinary complaint or not cooperate with an investigation or prosecution conducted by the disciplinary agency. Existing law prohibits a physician and surgeon from including specified provisions in an agreement to settle a civil dispute arising from his or her practice. Except as specified, existing law authorizes any interested person to petition a state agency requesting the adoption of a regulation.

This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards, bureaus, or programs, or an entity or person acting as an authorized agent of a licensee, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program, except as specified. A licensee in violation of these provisions would be subject to disciplinary action by the board, bureau, or program. The bill would also prohibit a board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil action to pay additional moneys to the benefit of any plaintiff in the civil action.

This bill would authorize a board, bureau, or program within the Department of Consumer Affairs to adopt a regulation exempting agreements to settle certain causes of action from these provisions.

The people of the State of California do enact as follows:

SECTION 1. Section 143.5 is added to the Business and Professions Code, to read:

143.5. (a) No licensee who is regulated by a board, bureau, or program within the Department of Consumer Affairs, nor an entity or person acting as an authorized agent of a licensee, shall include or permit to be included a provision in an agreement to settle a civil dispute, whether the agreement is made before or after the commencement of a civil action, that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program within the Department of Consumer Affairs that regulates the licensee or that requires the other party to withdraw a complaint from the department, board, bureau, or program within the Department of Consumer Affairs that regulates the licensee. A provision of that nature is void as against public policy, and any licensee who includes or permits to be included a provision of that nature in a settlement agreement is subject to disciplinary action by the board, bureau, or program.

(b) Any board, bureau, or program within the Department of Consumer Affairs that takes disciplinary action against a licensee or licensees based on a complaint or report that has also been the subject of a civil action and that has been settled for monetary damages providing for full and final satisfaction of the parties may not require its licensee or licensees to pay any additional sums to the benefit of any plaintiff in the civil action.

(c) As used in this section, "board" shall have the same meaning as defined in Section 22, and "licensee" means a person who has been granted a license, as that term is defined in Section 23.7.

(d) Notwithstanding any other law, upon granting a petition filed by a licensee or authorized agent of a licensee pursuant to Section 11340.6 of the Government Code, a board, bureau, or program within the Department of Consumer Affairs may, based upon evidence and legal authorities cited in the petition, adopt a regulation that does both of the following:

(1) Identifies a code section or jury instruction in a civil cause of action that has no relevance to the board's, bureau's, or program's enforcement responsibilities such that an agreement to settle such a cause of action based on that code section or jury instruction otherwise prohibited under subdivision (a) will not impair the board's, bureau's, or program's duty to protect the public.

(2) Exempts agreements to settle such a cause of action from the requirements of subdivision (a).

(e) This section shall not apply to a licensee subject to Section 2220.7.

SEC. 2. (a) Nothing in Section 143.5 of the Business and Professions Code shall be construed as limiting the discretion of a board, bureau, or program to decline to grant a petition or adopt a regulation.

(b) Nothing in Section 143.5 of the Business and Professions Code shall be construed as prohibiting a licensee from including in an agreement to settle a civil dispute any provision that is otherwise not prohibited.

O

Senate Bill No. 71

CHAPTER 728

An act to amend Sections 1917.1, 2028.5, 3627, 4076.5, 5092, 5093, 5094.6, 12104, and 19622.2 of, and to repeal Sections 2023, 2028, 2168.5, 3628, 3640.1, 5094.5, and 7139.7 of, the Business and Professions Code, to repeal Section 9527 of the Commercial Code, to amend Sections 14030.2, 14037.7, and 14076 of the Corporations Code, to amend Sections 1986, 17285, 17292.5, 20080, 22352, 24400, 42263, 48005.45, 52314, 53101, and 66040.7 of, and to repeal Sections 8007, 18884, 20081, 20082, and 22218.5 of, the Education Code, to amend Sections 7571 and 17555 of the Family Code, to amend Sections 456, 1727, 1850, 2079, 2086, 2861, and 7862 of, and to repeal Sections 1363.5, 1851, 3409, 3864, 4904, and 8610.10 of the Fish and Game Code, to repeal Sections 12794.5, 54446, and 58591 of the Food and Agricultural Code, to amend Sections 8169.5, 8587.5, 13103.5, 14453, 14613.7, 15438.6, 16367.5, 16428.6, 17562, 19849.11, 22959.6, 30061, and 64000 of, to repeal Sections 8164, 11535, 12805.4, 14051, 14556.36, 14714, 15813.6, 20233, and 20238 of, to repeal Article 3 (commencing with Section 11675) of Chapter 6 of Part 1 of Division 3 of Title 2 of, to repeal Article 5 (commencing with Section 14760) of Chapter 5 of Part 5.5 of Division 3 of Title 2 of, the Government Code, to repeal Sections 63.6 and 1159.5 of the Harbors and Navigation Code, to amend Sections 1342.7, 1357.16, 1626, 24275, 25150.7, 25174, 25299.50, 43105.5, 44003, 44014.6, 44024, 44081.6, 44100, 44104.5, 100500, 104200, 109951, 110552, 111198, 120910, 120955, 121285, 121340, 123516, 124174.5, 124590, 128600, and 130252 of, and to repeal Sections 25244.11, 25299.112, 102920, 103641, 120476, 124925, and 128557.5 of, the Health and Safety Code, to amend Section 15002 of, to repeal Section 1872.1 of the Insurance Code, to amend Sections 111, 3201.5, 3201.7, 3716.1, 4755, and 5502 of the Labor Code, to amend Section 431 of the Military and Veterans Code, to amend Sections 3049.5, 3050, 4801, 6131, 6242.6, 8061, 11166,11501, 13777, and 13847 of, and to repeal Section 1174.7 of, the Penal Code, to amend Sections 4124, 4137, 4214, 5004.5, 5095.53, 5096.162, 5096.242, 5096.320, 5096.340, 5631, 6217.8, 6331.5, 25401.9, 25722.5, 25722.8, 32556, 41821.5, and 71211 of, to amend, repeal, and add Section 30404 of, to repeal Sections 4612, 5632, 12290, 12291, 29773.5, 30533, 32556.2, 42889.3, 47123, and 5096.829 of, the Public Resources Code, to amend Section 185032 of, to repeal Section 9502 of, the Public Utilities Code, to amend Sections 8352.4 and 10752.2 of the Revenue and Taxation Code, to amend Sections 97, 164.56, 182.8, 2424, and 30161.5 of the Streets and Highways Code, to repeal Section 9907 of the Unemployment Insurance Code, to amend Sections 9250.7, 9250.14, and 9250.19 of the Vehicle Code, to amend Sections 162, 1228.2, 13369, 13396.9, 79083, and 79555 of, and to repeal Sections 138.9 and 78684.13 of, and to repeal Chapter 4 (commencing with Section 80250) of Division 27 of, the Water Code, to

amend Sections 1760.8, 4024, 6601, 10605.2, 10614.5, 10791, 11265.5, 11462, 14005.30, 14021.31, 14022.4, 14067, 14087.305, 14089, 14089.05, 14091.3, 14094.3, 14132, 14133.9, 14161, 14521.1, 14701, 18901.2, and 18993.8 of, and to repeal Section 19106 of, the Welfare and Institutions Code, to amend Section 2 of Chapter 133 of the Statutes of 1984, to amend Section 1 of Chapter 1436 of the Statutes of 1988, to amend Section 5 of Chapter 585 of the Statutes of 1993, to amend Section 3 of Chapter 1030 of the Statutes of 1993, to amend Section 1 of Chapter 561 of the Statutes of 1997, to amend Section 8 of Chapter 329 of the Statutes of 2000, to amend Section 2 of Chapter 790 of the Statutes of 2000, to amend Section 5 of Chapter 7 of the First Extraordinary Session of 2001, to amend Section 24 of Chapter 1127 of the Statutes of 2002, to amend Section 37 of Chapter 80 of the Statutes of 2005, to amend Item 0690-102-0001 of Section 2.00 of the Budget Act of 2006 (Chapter 47 of the Statutes of 2006), to amend Item 0690-102-0001 of Section 2.00 of the Budget Act of 2007 (Chapter 171 of the Statutes of 2007), to amend Section 41 of Chapter 177 of the Statutes of 2007, to repeal Section 3 of Chapter 1397 of the Statutes of 1988, to repeal Resolution Chapter 173 of the Statutes of 1989, to repeal Resolution Chapter 12 of the Statutes of 1990, to repeal Section 1 of Chapter 452 of the Statutes of 1996, to repeal Section 3 of Chapter 791 of the Statutes of 1997, to repeal Section 51 of Chapter 171 of the Statutes of 2001, to repeal Section 2 of Chapter 87 of the Statutes of 2003, to repeal the second Section 2 of Chapter 642 of the Statutes of 2007, to repeal Section 72 of Chapter 758 of the Statutes of 2008, to repeal Section 38 of Chapter 759 of the Statutes of 2008, to repeal Section 173 of Chapter 717 of the Statutes of 2010, and to repeal Sections 37 and 38 of Chapter 6 of the Statutes of 2011, relating to state government.

[Approved by Governor September 28, 2012. Filed with Secretary of State September 28, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

SB 71, Leno. State agencies: boards, commissions, and reports.

(1) Existing law requires various state agencies to submit certain reports, plans, evaluations, and other similar documents to the Legislature and other state agencies.

This bill would eliminate the requirement that certain state agencies submit certain reports to the Legislature and other state agencies relating to a variety of subjects. The bill would also modify various requirements of certain reports by, among other ways, requiring specified reports be placed on the Internet Web site of the reporting agency rather than submitted to the Legislature or other state agencies, requiring certain agencies to collaborate with other agencies in preparing specified reports, consolidating certain reports, deleting the requirement that specified state agencies make specified information available on their Internet Web sites, and transferring reporting duties from one agency to another.

This bill would make various conforming changes.

(2) Existing law requires the Secretary of the Natural Resources Agency to convene a committee to develop and submit to the Governor and the Legislature, on or before December 31, 2008, a Strategic Vision for a Sustainable Sacramento-San Joaquin Delta.

This bill would repeal the provisions establishing that committee.

(3) Existing law, the Naturopathic Doctors Act, provides for the licensure and regulation of naturopathic doctors by the Naturopathic Medicine Committee within the Osteopathic Medical Board of California. Existing law also requires the committee to establish a naturopathic childbirth attendance advisory subcommittee to issue recommendations concerning the practice of naturopathic childbirth attendance based upon a review of naturopathic medical education and training, as specified.

This bill would repeal the provisions providing for the establishment of this subcommittee.

(4) Existing law provides for the licensure and regulation of accountants by the California Board of Accountancy. Existing law requires an applicant for an accountancy license to complete a minimum of 24 semester units in accounting subjects and a minimum of 24 semester units in business-related subjects. Existing law, on and after January 1, 2014, requires an applicant for an accountancy license to complete an additional 10 semester units or 15 quarter units in ethics study and 20 units in accounting study. Existing law establishes the Advisory Committee on Accounting Ethics Curriculum within the jurisdiction of the board to, by January 1, 2012, recommend guidelines for the ethics study requirement to the board.

This bill would repeal the provisions establishing the Advisory Committee on Accounting Ethics Curriculum and would make related conforming and technical changes.

(5) Existing law establishes the Committee of Executive Salaries, and requires the committee to study issues relating to executive salaries in the private and public sector, and to report to the Legislature on a biannual basis its findings and recommended changes.

This bill would repeal the provisions establishing the committee.

(6) Existing law requires the State Department of Public Health to regulate certain types of candy, as defined, and requires the department to convene an interagency collaborative to serve as an oversight committee for the implementation of those provisions and to work with the department in establishing and revising the required standards.

This bill would repeal those provisions establishing the interagency collaborative and would make technical and conforming changes.

(7) Existing law creates the Fraud Division within the Department of Insurance to enforce specific provisions of law regarding crimes against insured property and insurance fraud reporting. Existing law creates the advisory committee on automobile insurance fraud and economic automobile theft prevention within the division to recommend ways to coordinate the investigation, prosecution, and prevention of automobile insurance claims fraud, and to provide assistance to the division towards implementing the

goal of reducing the frequency and severity of fraudulent automobile insurance claims, among other things.

This bill would repeal the provisions establishing the advisory committee.

(8) This bill would make various technical and conforming changes.

The people of the State of California do enact as follows:

SECTION 1. Section 1917.1 of the Business and Professions Code is amended to read:

1917.1. (a) The committee may grant a license as a registered dental hygienist to an applicant who has not taken a clinical examination before the committee, if the applicant submits all of the following to the committee:

(1) A completed application form and all fees required by the committee.

(2) Proof of a current license as a registered dental hygienist issued by another state that is not revoked, suspended, or otherwise restricted.

(3) Proof that the applicant has been in clinical practice as a registered dental hygienist or has been a full-time faculty member in an accredited dental hygiene education program for a minimum of 750 hours per year for at least five years preceding the date of his or her application under this section. The clinical practice requirement shall be deemed met if the applicant provides proof of at least three years of clinical practice and commits to completing the remaining two years of clinical practice by filing with the committee a copy of a pending contract to practice dental hygiene in any of the following facilities:

(A) A primary care clinic licensed under subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic exempt from licensure pursuant to subdivision (c) of Section 1206 of the Health and Safety Code.

(C) A clinic owned or operated by a public hospital or health system.

(D) A clinic owned and operated by a hospital that maintains the primary contract with a county government to fill the county's role under Section 17000 of the Welfare and Institutions Code.

(4) Satisfactory performance on a California law and ethics examination and any examination that may be required by the committee.

(5) Proof that the applicant has not been subject to disciplinary action by any state in which he or she is or has been previously licensed as a registered dental hygienist or dentist. If the applicant has been subject to disciplinary action, the committee shall review that action to determine if it warrants refusal to issue a license to the applicant.

(6) Proof of graduation from a school of dental hygiene accredited by the Commission on Dental Accreditation.

(7) Proof of satisfactory completion of the Dental Hygiene National Board Examination and of a state or regional clinical licensure examination.

(8) Proof that the applicant has not failed the examination for licensure to practice dental hygiene under this chapter more than once or once within

five years prior to the date of his or her application for a license under this section.

(9) Documentation of completion of a minimum of 25 units of continuing education earned in the two years preceding application, including completion of any continuing education requirements imposed by the committee on registered dental hygienists licensed in this state at the time of application.

(10) Any other information as specified by the committee to the extent that it is required of applicants for licensure by examination under this article.

(b) The committee may periodically request verification of compliance with the requirements of paragraph (3) of subdivision (a), and may revoke the license upon a finding that the employment requirement or any other requirement of paragraph (3) of subdivision (a) has not been met.

(c) The committee shall provide in the application packet to each out-of-state dental hygienist pursuant to this section the following information:

(1) The location of dental manpower shortage areas in the state.

(2) Any not-for-profit clinics, public hospitals, and accredited dental hygiene education programs seeking to contract with licensees for dental hygiene service delivery or training purposes.

SEC. 2. Section 2023 of the Business and Professions Code is repealed.

SEC. 3. Section 2028 of the Business and Professions Code is repealed.

SEC. 4. Section 2028.5 of the Business and Professions Code is amended to read:

2028.5. (a) The board may establish a pilot program to expand the practice of telemedicine in this state.

(b) To implement this pilot program, the board may convene a working group of interested parties from the public and private sectors, including, but not limited to, state health-related agencies, health care providers, health plan administrators, information technology groups, and groups representing health care consumers.

(c) The purpose of the pilot program shall be to develop methods, using a telemedicine model, to deliver throughout the state health care to persons with chronic diseases as well as information on the best practices for chronic disease management services and techniques and other health care information as deemed appropriate.

SEC. 5. Section 2168.5 of the Business and Professions Code is repealed.

SEC. 6. Section 3627 of the Business and Professions Code is amended to read:

3627. (a) The committee shall establish a naturopathic formulary advisory subcommittee to determine a naturopathic formulary based upon a review of naturopathic medical education and training.

(b) The naturopathic formulary advisory subcommittee shall be composed of an equal number of representatives from the clinical and academic settings of physicians and surgeons, pharmacists, and naturopathic doctors.

(c) The naturopathic formulary advisory subcommittee shall review naturopathic education, training, and practice and make specific recommendations regarding the prescribing, ordering, and furnishing authority of a naturopathic doctor and the required supervision and protocols for those functions.

SEC. 7. Section 3628 of the Business and Professions Code is repealed.

SEC. 8. Section 3640.1 of the Business and Professions Code is repealed.

SEC. 9. Section 4076.5 of the Business and Professions Code is amended to read:

4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(1) Medical literacy research that points to increased understandability of labels.

(2) Improved directions for use.

(3) Improved font types and sizes.

(4) Placement of information that is patient-centered.

(5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:

(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.

(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.

(C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.

(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.

(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

SEC. 10. Section 5092 of the Business and Professions Code is amended to read:

5092. (a) To qualify for the certified public accountant license, an applicant who is applying under this section shall meet the education, examination, and experience requirements specified in subdivisions (b), (c), and (d), or otherwise prescribed pursuant to this article. The board may adopt regulations as necessary to implement this section.

(b) An applicant for the certified public accountant license shall present satisfactory evidence that the applicant has completed a baccalaureate or higher degree conferred by a college or university, meeting, at a minimum, the standards described in Section 5094, the total educational program to include a minimum of 24 semester units in accounting subjects and 24 semester units in business related subjects. This evidence shall be provided prior to admission to the examination for the certified public accountant license, except that an applicant who applied, qualified, and sat for at least two subjects of the examination for the certified public accountant license before May 15, 2002, may provide this evidence at the time of application for licensure.

(c) An applicant for the certified public accountant license shall pass an examination prescribed by the board pursuant to this article.

(d) The applicant shall show, to the satisfaction of the board, that the applicant has had two years of qualifying experience. This experience may include providing any type of service or advice involving the use of accounting, attest, compilation, management advisory, financial advisory, tax, or consulting skills. To be qualifying under this section, experience shall have been performed in accordance with applicable professional standards. Experience in public accounting shall be completed under the supervision or in the employ of a person licensed or otherwise having comparable authority under the laws of any state or country to engage in the practice of public accountancy. Experience in private or governmental accounting or auditing shall be completed under the supervision of an individual licensed by a state to engage in the practice of public accountancy.

(e) This section shall become inoperative on January 1, 2014, but shall become or remain operative if either the educational requirements in ethics study and accounting study established by subdivision (b) of Section 5093 and Section 5094.6 are reduced or eliminated or if the practice privilege requirements of Sections 5096 to 5096.15, inclusive, are amended or repealed.

Senate Bill No. 1095

CHAPTER 454

An act to amend Sections 4190 and 4195 of, and to amend the heading of Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of, the Business and Professions Code, and to amend Section 1248.35 of the Health and Safety Code, relating to pharmacy.

[Approved by Governor September 22, 2012. Filed with Secretary of State September 22, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1095, Rubio. Pharmacy: clinics.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy and makes a knowing violation of its provisions a crime. Existing law authorizes a surgical clinic, as defined, that is licensed by the board to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the surgical clinic. Existing law prohibits a surgical clinic from operating without a license issued by the board. Existing law requires these surgical clinics to comply with various regulatory requirements and to maintain specified records. Existing law authorizes the board to inspect a surgical clinic at any time in order to determine whether a surgical clinic is operating in compliance with certain requirements.

This bill would expand these provisions to additionally authorize an outpatient setting or an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing, subject to the requirements applicable to surgical clinics. The bill would delete the requirement that a surgical clinic be licensed by the board in order to operate. The bill would specify that the board is authorized to inspect only an outpatient setting, an ambulatory surgical care center, or a surgical clinic that is licensed by the board.

Existing law requires every outpatient setting which is accredited to be inspected by the accreditation agency, as defined, and authorizes an outpatient setting to be inspected by the Medical Board of California. Existing law requires the accreditation agency to provide the outpatient setting with notice of any deficiencies and requires the outpatient setting to agree with the accreditation agency on a plan of correction. Existing law requires the accrediting agency to send a list of deficiencies and the corrective action to the Medical Board of California. Existing law requires the accreditation agency to report to the Medical Board of California if the outpatient setting has been issued a reprimand or if the outpatient setting's certification of accreditation has been suspended or revoked or if the

outpatient setting has been placed on probation. Existing law makes a willful violation of those provisions governing outpatient settings a crime.

This bill would additionally require the accrediting agency to send a list of deficiencies and the corrective action to the California State Board of Pharmacy if an outpatient setting is licensed to purchase drugs at wholesale for administration or dispensing, as described above. The bill would also require the accreditation agency to report to the California State Board of Pharmacy if an outpatient setting has been issued such a license and the outpatient setting has been issued a reprimand or if the outpatient setting's certification of accreditation has been suspended or revoked or if the outpatient setting has been placed on probation.

Because a knowing violation of these requirements by outpatient settings and ambulatory surgical centers, and a willful violation of these requirements by accreditation agencies, would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. This act shall be known and may be cited as the California Outpatient Pharmacy Patient Safety and Improvement Act.

SEC. 2. The heading of Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:

Article 14. Clinics

SEC. 3. Section 4190 of the Business and Professions Code is amended to read:

4190. (a) For the purposes of this article, "clinic" means a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

(b) A clinic licensed by the board may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as provided in subdivision (c). A separate license shall be required for each clinic location. A clinic licensed by the board shall notify the board of any change in the clinic's address on a form furnished by the board. The clinic shall keep records of the kind and

amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(c) The drug distribution service of a clinic shall be limited to the use of drugs for administration to the patients of the clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(d) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board.

(e) If a clinic is licensed by the board, any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

(f) Nothing in this section shall limit the ability of a physician and surgeon to prescribe, dispense, administer, or furnish drugs at a clinic as provided in Sections 2241.5, 2242, and 4170.

SEC. 4. Section 4195 of the Business and Professions Code is amended to read:

4195. The board shall have the authority to inspect a clinic that is licensed pursuant to this article at any time in order to determine whether the clinic is, or is not, operating in compliance with this article and all other provisions of the law.

SEC. 5. Section 1248.35 of the Health and Safety Code is amended to read:

1248.35. (a) Every outpatient setting which is accredited shall be inspected by the accreditation agency and may also be inspected by the Medical Board of California. The Medical Board of California shall ensure that accreditation agencies inspect outpatient settings.

(b) Unless otherwise specified, the following requirements apply to inspections described in subdivision (a).

(1) The frequency of inspection shall depend upon the type and complexity of the outpatient setting to be inspected.

(2) Inspections shall be conducted no less often than once every three years by the accreditation agency and as often as necessary by the Medical Board of California to ensure the quality of care provided.

(3) The Medical Board of California or the accreditation agency may enter and inspect any outpatient setting that is accredited by an accreditation agency at any reasonable time to ensure compliance with, or investigate an alleged violation of, any standard of the accreditation agency or any provision of this chapter.

(c) If an accreditation agency determines, as a result of its inspection, that an outpatient setting is not in compliance with the standards under which it was approved, the accreditation agency may do any of the following:

(1) Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the outpatient setting's accreditation.

(2) Issue a reprimand.

(3) Place the outpatient setting on probation, during which time the setting shall successfully institute and complete a plan of correction, approved by the board or the accreditation agency, to correct the deficiencies.

(4) Suspend or revoke the outpatient setting's certification of accreditation.

(d) (1) Except as is otherwise provided in this subdivision, before suspending or revoking a certificate of accreditation under this chapter, the accreditation agency shall provide the outpatient setting with notice of any deficiencies and the outpatient setting shall agree with the accreditation agency on a plan of correction that shall give the outpatient setting reasonable time to supply information demonstrating compliance with the standards of the accreditation agency in compliance with this chapter, as well as the opportunity for a hearing on the matter upon the request of the outpatient setting. During the allotted time to correct the deficiencies, the plan of correction, which includes the deficiencies, shall be conspicuously posted by the outpatient setting in a location accessible to public view. Within 10 days after the adoption of the plan of correction, the accrediting agency shall send a list of deficiencies and the corrective action to be taken to the board and to the California State Board of Pharmacy if an outpatient setting is licensed pursuant to Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code. The accreditation agency may immediately suspend the certificate of accreditation before providing notice and an opportunity to be heard, but only when failure to take the action may result in imminent danger to the health of an individual. In such cases, the accreditation agency shall provide subsequent notice and an opportunity to be heard.

(2) If an outpatient setting does not comply with a corrective action within a timeframe specified by the accrediting agency, the accrediting agency shall issue a reprimand, and may either place the outpatient setting on probation or suspend or revoke the accreditation of the outpatient setting, and shall notify the board of its action. This section shall not be deemed to prohibit an outpatient setting that is unable to correct the deficiencies, as specified in the plan of correction, for reasons beyond its control, from voluntarily surrendering its accreditation prior to initiation of any suspension or revocation proceeding.

(e) The accreditation agency shall, within 24 hours, report to the board if the outpatient setting has been issued a reprimand or if the outpatient setting's certification of accreditation has been suspended or revoked or if the outpatient setting has been placed on probation. If an outpatient setting has been issued a license by the California State Board of Pharmacy pursuant

to Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of the Business and Professions Code, the accreditation agency shall also send this report to the California State Board of Pharmacy within 24 hours.

(f) The accreditation agency, upon receipt of a complaint from the board that an outpatient setting poses an immediate risk to public safety, shall inspect the outpatient setting and report its findings of inspection to the board within five business days. If an accreditation agency receives any other complaint from the board, it shall investigate the outpatient setting and report its findings of investigation to the board within 30 days.

(g) Reports on the results of any inspection shall be kept on file with the board and the accreditation agency along with the plan of correction and the comments of the outpatient setting. The inspection report may include a recommendation for reinspection. All final inspection reports, which include the lists of deficiencies, plans of correction or requirements for improvements and correction, and corrective action completed, shall be public records open to public inspection.

(h) If one accrediting agency denies accreditation, or revokes or suspends the accreditation of an outpatient setting, this action shall apply to all other accrediting agencies. An outpatient setting that is denied accreditation is permitted to reapply for accreditation with the same accrediting agency. The outpatient setting also may apply for accreditation from another accrediting agency, but only if it discloses the full accreditation report of the accrediting agency that denied accreditation. Any outpatient setting that has been denied accreditation shall disclose the accreditation report to any other accrediting agency to which it submits an application. The new accrediting agency shall ensure that all deficiencies have been corrected and conduct a new onsite inspection consistent with the standards specified in this chapter.

(i) If an outpatient setting's certification of accreditation has been suspended or revoked, or if the accreditation has been denied, the accreditation agency shall do all of the following:

(1) Notify the board of the action.

(2) Send a notification letter to the outpatient setting of the action. The notification letter shall state that the setting is no longer allowed to perform procedures that require outpatient setting accreditation.

(3) Require the outpatient setting to remove its accreditation certification and to post the notification letter in a conspicuous location, accessible to public view.

(j) The board may take any appropriate action it deems necessary pursuant to Section 1248.7 if an outpatient setting's certification of accreditation has been suspended or revoked, or if accreditation has been denied.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime

within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Senate Bill No. 1099

CHAPTER 295

An act to amend Sections 11343, 11343.4, and 11344 of the Government Code, and to amend Section 116064 of the Health and Safety Code, relating to regulations.

[Approved by Governor September 11, 2012. Filed with Secretary of State September 11, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1099, Wright. Regulations.

(1) The Administrative Procedure Act generally sets forth the requirements for the adoption, publication, review, and implementation of regulations by state agencies. The act specifically provides that a regulation or order of repeal required to be filed with the Secretary of State shall become effective on the 30th day after the date of filing, subject to certain exceptions.

This bill would instead provide that a regulation or order of repeal is effective on January 1, April 1, July 1, or October 1, as specified, subject to certain exceptions, including, but not limited to, specified regulations adopted by the Fish and Game Commission.

(2) The act requires the Office of Administrative Law to make a free copy of the full text of the California Code of Regulations available on its Internet Web site.

This bill would also require the office to provide on its Internet Web site a list of, and a link to the full text of, each regulation filed with the Secretary of State that is pending effectiveness, as specified.

(3) Existing law requires that every state agency subject to the act that maintains an Internet Web site or similar forum for the electronic publication or distribution of written material publish on that Internet Web site or other forum specified information regarding a proposed regulation or regulatory repeal or amendment.

This bill would also require a state agency to post on its Internet Web site each regulation that is filed with the Secretary of State, as specified, and to send to the office the Internet Web site link of the regulation. The bill would not apply to a state agency that does not maintain an Internet Web site.

This bill would also make a conforming change.

This bill would incorporate additional changes in Section 116064 of the Health and Safety Code, proposed by AB 2114, to be operative only if AB 2114 and this bill are both chaptered and become effective on or before January 1, 2013, and this bill is chaptered last.

The people of the State of California do enact as follows:

SECTION 1. Section 11343 of the Government Code is amended to read:

11343. Every state agency shall:

(a) Transmit to the office for filing with the Secretary of State a certified copy of every regulation adopted or amended by it except one that is a building standard.

(b) Transmit to the office for filing with the Secretary of State a certified copy of every order of repeal of a regulation required to be filed under subdivision (a).

(c) (1) Within 15 days of the office filing a state agency's regulation with the Secretary of State, post the regulation on its Internet Web site in an easily marked and identifiable location. The state agency shall keep the regulation on its Internet Web site for at least six months from the date the regulation is filed with the Secretary of State.

(2) Within five days of posting, the state agency shall send to the office the Internet Web site link of each regulation that the agency posts on its Internet Web site pursuant to paragraph (1).

(3) This subdivision shall not apply to a state agency that does not maintain an Internet Web site.

(d) Deliver to the office, at the time of transmittal for filing a regulation or order of repeal, six duplicate copies of the regulation or order of repeal, together with a citation of the authority pursuant to which it or any part thereof was adopted.

(e) Deliver to the office a copy of the notice of proposed action required by Section 11346.4.

(f) Transmit to the California Building Standards Commission for approval a certified copy of every regulation, or order of repeal of a regulation, that is a building standard, together with a citation of authority pursuant to which it or any part thereof was adopted, a copy of the notice of proposed action required by Section 11346.4, and any other records prescribed by the State Building Standards Law (Part 2.5 (commencing with Section 18901) of Division 13 of the Health and Safety Code).

(g) Whenever a certification is required by this section, it shall be made by the head of the state agency that is adopting, amending, or repealing the regulation, or by a designee of the agency head, and the certification and delegation shall be in writing.

SEC. 2. Section 11343.4 of the Government Code is amended to read:

11343.4. (a) Except as otherwise provided in subdivision (b), a regulation or an order of repeal required to be filed with the Secretary of State shall become effective on a quarterly basis as follows:

(1) January 1 if the regulation or order of repeal is filed on September 1 to November 30, inclusive.

(2) April 1 if the regulation or order of repeal is filed on December 1 to February 29, inclusive.

(3) July 1 if the regulation or order of repeal is filed on March 1 to May 31, inclusive.

(4) October 1 if the regulation or order of repeal is filed on June 1 to August 31, inclusive.

(b) The effective dates in subdivision (a) shall not apply in all of the following:

(1) The effective date is specifically provided by the statute pursuant to which the regulation or order of repeal was adopted, in which event it becomes effective on the day prescribed by the statute.

(2) A later date is prescribed by the state agency in a written instrument filed with, or as part of, the regulation or order of repeal.

(3) The agency makes a written request to the office demonstrating good cause for an earlier effective date, in which case the office may prescribe an earlier date.

(4) (A) A regulation adopted by the Fish and Game Commission pursuant to Article 1 (commencing with Section 200) of Chapter 2 of Division 1 of the Fish and Game Code.

(B) A regulation adopted by the Fish and Game Commission that requires a different effective date in order to conform to a federal regulation.

SEC. 3. Section 11344 of the Government Code is amended to read:

11344. The office shall do all of the following:

(a) Provide for the official compilation, printing, and publication of adoption, amendment, or repeal of regulations, which shall be known as the California Code of Regulations. On and after July 1, 1998, the office shall make available on the Internet, free of charge, the full text of the California Code of Regulations, and may contract with another state agency or a private entity in order to provide this service.

(b) Make available on its Internet Web site a list of, and a link to the full text of, each regulation filed with the Secretary of State that is pending effectiveness pursuant to Section 11343.4.

(c) Provide for the compilation, printing, and publication of weekly updates of the California Code of Regulations. This publication shall be known as the California Code of Regulations Supplement and shall contain amendments to the code.

(d) Provide for the publication dates and manner and form in which regulations shall be printed and distributed and ensure that regulations are available in printed form at the earliest practicable date after filing with the Secretary of State.

(e) Ensure that each regulation is printed together with a reference to the statutory authority pursuant to which it was enacted and the specific statute or other provision of law which the regulation is implementing, interpreting, or making specific.

SEC. 4. Section 116064 of the Health and Safety Code is amended to read:

116064. (a) As used in this section the following words have the following meanings:

(1) (A) "Public wading pool" means a pool that meets all of the following criteria:

(i) It has a maximum water depth not exceeding 18 inches.

(ii) It is a pool other than a pool that is located on the premises of a one-unit or two-unit residence, intended solely for the use of the residents or guests.

(B) "Public wading pool" includes, but is not limited to, a pool owned or operated by private persons or agencies, or by state or local governmental agencies.

(C) "Public wading pool" includes, but is not limited to, a pool located in an apartment house, hotel, or similar setting, that is intended for the use of residents or guests.

(2) "Alteration" means any of the following:

(A) To change, modify, or rearrange the structural parts or the design.

(B) To enlarge.

(C) To move the location of.

(D) To install a new water circulation system.

(E) To make any repairs costing fifty dollars ($50) or more to an existing circulation system.

(b) A public wading pool shall have at least two circulation drains per pump that are hydraulically balanced and symmetrically plumbed through one or more "T" fittings, and are separated by a distance of at least three feet in any dimension between the drains.

(c) All public wading pool main drain suction outlets that are under 12 inches across shall be covered with antivortex grates or similar protective devices. All main drain suction outlets shall be covered with grates or antivortex plates that cannot be removed except with the use of tools. Slots or openings in the grates or similar protective devices shall be of a shape, area, and arrangement that would prevent physical entrapment and would not pose any suction hazard to bathers.

(d) (1) The State Department of Health Services may adopt regulations pursuant to this section.

(2) The regulations may include, but not be limited to, standards permitting the use of alternative devices or safeguards, or incorporating new technologies, that produce, at a minimum, equivalent protection against entrapment and suction hazard, whenever these devices, safeguards, or technologies become available to the public.

(3) Regulations adopted pursuant to this section constitute building standards and shall be forwarded pursuant to Section 11343 of the Government Code to the California Building Standards Commission for approval as set forth in Section 18907 of the Health and Safety Code.

(e) The California Building Standards Commission shall approve the building standards as set forth in this section and publish them in the California Building Standards Code by November 1, 1999. The commission shall publish the text of this section in Title 24 of the California Code of Regulations, Part 2, Chapter 31B, requirements for public swimming pools, with the following note: "NOTE: These building standards are in statute

but have not been adopted through the regulatory process." Enforcement of the standards set forth in this section does not depend upon adoption of regulations, therefore, enforcement agencies shall enforce the standards pursuant to the timeline set forth in this section prior to adoption of related regulations.

(f) The maximum velocity in the pump suction hydraulic system shall not exceed six feet per second when 100 percent of the pump's flow comes from the main drain system and any main drain suction fitting in the system is completely blocked.

(g) On and after January 1, 1998, all newly constructed public wading pools shall be constructed in compliance with this section.

(h) Commencing January 1, 1998, whenever a construction permit is issued for alteration of an existing public wading pool, it shall be retrofitted so as to be in compliance with this section.

(i) By January 1, 2000, every public wading pool, regardless of the date of original construction, shall be retrofitted to comply with this section.

SEC. 4.5. Section 116064 of the Health and Safety Code is amended to read:

116064. (a) As used in this section the following words have the following meanings:

(1) (A) "Public wading pool" means a pool that meets all of the following criteria:

(i) It has a maximum water depth not exceeding 18 inches.

(ii) It is a pool other than a pool that is located on the premises of a one-unit or two-unit residence, intended solely for the use of the residents or guests.

(B) "Public wading pool" includes, but is not limited to, a pool owned or operated by private persons or agencies, or by state or local governmental agencies.

(C) "Public wading pool" includes, but is not limited to, a pool located in an apartment house, hotel, or similar setting, that is intended for the use of residents or guests.

(2) "Alteration" means any of the following:

(A) To change, modify, or rearrange the structural parts or the design.

(B) To enlarge.

(C) To move the location of.

(D) To install a new water circulation system.

(E) To make any repairs costing fifty dollars ($50) or more to an existing circulation system.

(3) "ANSI/APSP performance standard" means a standard that is accredited by the American National Standards Institute (ANSI) and published by the Association of Pool and Spa Professionals (APSP).

(4) "Suction outlet" means a fitting or fixture typically located at the bottom or on the sides of a swimming pool that conducts water to a recirculating pump.

(b) A public wading pool shall have at least two circulation suction outlets per pump that are hydraulically balanced and symmetrically plumbed

through one or more "T" fittings, and are separated by a distance of at least three feet in any dimension between the suction outlets.

(c) All public wading pool suction outlets shall be covered with antivortex grates or similar protective devices. All suction outlets shall be covered with grates or antivortex plates that cannot be removed except with the use of tools. Slots or openings in the grates or similar protective devices shall be of a shape, area, and arrangement that would prevent physical entrapment and would not pose any suction hazard to bathers.

(d) (1) The State Department of Health Services may adopt regulations pursuant to this section.

(2) The regulations may include, but not be limited to, standards permitting the use of alternative devices or safeguards, or incorporating new technologies, that produce, at a minimum, equivalent protection against entrapment and suction hazard, whenever these devices, safeguards, or technologies become available to the public.

(3) Regulations adopted pursuant to this section constitute building standards and shall be forwarded pursuant to Section 11343 of the Government Code to the California Building Standards Commission for approval as set forth in Section 18907 of the Health and Safety Code.

(e) The California Building Standards Commission shall approve the building standards as set forth in this section and publish them in the California Building Standards Code by November 1, 1999. The commission shall publish the text of this section in Title 24 of the California Code of Regulations, Part 2, Chapter 31B, requirements for public swimming pools, with the following note: "NOTE: These building standards are in statute but have not been adopted through the regulatory process." Enforcement of the standards set forth in this section does not depend upon adoption of regulations, therefore, enforcement agencies shall enforce the standards pursuant to the timeline set forth in this section prior to adoption of related regulations.

(f) The maximum velocity in the pump suction hydraulic system shall not exceed six feet per second when 100 percent of the pump's flow comes from the circulation system and any suction outlet in the system is completely blocked.

(g) On and after January 1, 1998, all newly constructed public wading pools shall be constructed in compliance with this section.

(h) Commencing January 1, 1998, whenever a construction permit is issued for alteration of an existing public wading pool, it shall be retrofitted so as to be in compliance with this section.

(i) By January 1, 2000, every public wading pool, regardless of the date of original construction, shall be retrofitted to comply with this section.

SEC. 5. Section 4.5 of this bill incorporates amendments to Section 116064 of the Health and Safety Code proposed by both this bill and Assembly Bill 2114. It shall become operative only if (1) both bills are enacted and become effective on or before January 1, 2013, (2) each bill amends Section 116064 of the Health and Safety Code, and (3) this bill is

enacted after Assembly Bill 2114, in which case Section 4 of this bill shall not become operative.

O

Senate Bill No. 1236

CHAPTER 332

An act to amend Sections 800, 801.01, 802.1, 802.5, 803, 803.1, 803.5, 803.6, 805, 2006, 2335, 2450.3, 2460, 2465, 2470, 2472, 2475, 2484, 2493, 2496, 2497.5, 2602, 2607.5, 2920, 2933, 3501, 3502, 3502.1, 3502.3, 3502.5, 3504, 3504.1, 3505, 3506, 3507, 3508, 3509, 3509.5, 3510, 3511, 3512, 3513, 3514.1, 3516, 3516.5, 3517, 3518, 3519, 3519.5, 3520, 3521, 3521.1, 3521.2, 3521.5, 3522, 3523, 3524, 3524.5, 3526, 3527, 3529, 3530, 3531, 3533, 3534, 3534.1, 3534.2, 3534.3, 3534.4, 3534.5, 3534.6, 3534.7, 3534.9, 3534.10, 3535, 3537.10, 3537.20, 3537.30, 3537.50, 3540, 3546, 4001, 4003, 4928, 4934, 4939, 4990, 4990.04, 8000, 8005, 8027, 8030.2, 8030.5, 9812.5, 9830.5, 9832.5, 9847.5, 9849, 9851, 9853, 9860, 9862.5, 9863, and 9873 of, and to add Section 3521.3 to, the Business and Professions Code, and to amend Sections 12529, 12529.5, and 12529.6 of the Government Code, relating to professions and vocations, and making an appropriation therefor.

[Approved by Governor September 14, 2012. Filed with Secretary of State September 14, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1236, Price. Professions and vocations.

(1) Existing law, until January 1, 2013, declares that using a vertical enforcement and prosecution model for the Medical Board of California's investigations is in the best interests of the people of California. Under existing law, a vertical enforcement and prosecution model is described as the joint assignment of a complaint to a board investigator and to a deputy attorney general responsible for prosecuting the case if the investigation results in the filing of an accusation. Existing law requires the board to, among other things, establish and implement a plan to locate specified staff in the same offices in order to carry out the intent of the vertical enforcement and prosecution model.

This bill would extend the operation of these provisions to January 1, 2014, and would also make a conforming change in that regard.

(2) Existing law provides for the certification and regulation of podiatrists by the California Board of Podiatric Medicine within the jurisdiction of the Medical Board of California. Under existing law, the California Board of Podiatric Medicine will be repealed on January 1, 2013. Existing law requires that boards scheduled for repeal be reviewed by the Joint Sunset Review Committee of the Legislature.

This bill would extend the operation of the California Board of Podiatric Medicine until January 1, 2017. The bill would specify that the board is subject to review by the appropriate policy committees of the Legislature.

The bill would revise provisions regarding the examination of applicants for certification to practice podiatric medicine.

(3) Existing law establishes the Physician Assistant Committee within the jurisdiction of the Medical Board of California and provides for its membership, operation, duties, and powers with respect to licensure and regulation of physician assistants, including requirements for the payment of license renewal fees. Under existing law, the committee will be repealed on January 1, 2013.

This bill would rename the committee as the Physician Assistant Board, make various conforming changes relative to this change in designation, and extend the operation of the board until January 1, 2017. The bill would revise the composition of the board and would specify that the board is subject to review by the appropriate policy committees of the Legislature. The bill would allow the board to establish, by regulation, a system for placement of a licensee on retired status, as specified.

(4) Existing law specifies reports to be made and procedures to be followed when a coroner receives information, as specified, that a death may be the result of a physician and surgeon's, or podiatrist's gross negligence or incompetence, and in connection with disciplinary actions against those licensees.

This bill would expand those provisions to include conduct of a physician assistant.

(5) Existing law requires a physician and surgeon, osteopathic physician and surgeon, and a doctor of podiatric medicine to report to his or her licensing board the occurrence of an indictment or information charging a felony against the licensee or the conviction of the licensee of a felony or misdemeanor. Under existing law the failure of those licensees to submit the required report is a crime.

This bill would impose that requirement on a physician assistant. Because a violation of this requirement by a physician assistant would be a crime, this bill would impose a state-mandated local program.

(6) Existing law, the Physical Therapy Practice Act, provides for the licensure and regulation of physical therapists by the Physical Therapy Board of California. Existing law authorizes the board to appoint an executive officer. Existing law makes these provisions inoperative on July 1, 2013, and repealed on January 1, 2014. Under existing law, boards scheduled for repeal are required to be evaluated by the Joint Sunset Review Committee.

This bill would delete the inoperative date and would instead repeal these provisions on January 1, 2014. The bill would also specify that this board would be subject to review by the appropriate policy committees of the Legislature.

(7) Existing law, the Naturopathic Doctors Act, provides for the licensure and regulation of naturopathic doctors by the Naturopathic Medicine Committee within the Osteopathic Medical Board of California. Existing law repeals these provisions on January 1, 2014. Under existing law, boards

scheduled for repeal are required to be evaluated by the Joint Sunset Review Committee.

This bill would make a conforming change with regard to the operation of these provisions until January 1, 2014, and the bill would also specify that this board would be subject to review by the appropriate policy committees of the Legislature.

(8) Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, pharmacists, pharmacy technicians, wholesalers of dangerous drugs or devices, and others by the California State Board of Pharmacy. Existing law authorizes the board to appoint an executive officer. Under existing law, the board and its authority to appoint an executive officer will be repealed on January 1, 2013. Under existing law, boards scheduled for repeal are required to be evaluated by the Joint Sunset Review Committee.

This bill would extend the operation of the California State Board of Pharmacy and its authority to appoint an executive officer until January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.

(9) Existing law provides for the licensure and regulation of psychologists by the Board of Psychology. Existing law provides for the licensure and regulation of licensed educational psychologists, clinical social workers, marriage and family therapists, and licensed professional clinical counselors by the Board of Behavioral Sciences within the Department of Consumer Affairs. Existing law specifies the composition of each board and requires or authorizes each board to employ an executive officer. Existing law repeals these provisions on January 1, 2013. Under existing law, boards scheduled for repeal are required to be evaluated by the Joint Sunset Review Committee.

This bill would extend the operation of these provisions until January 1, 2017. This bill would specify that each board is subject to review by the appropriate policy committees of the Legislature.

(10) Existing law, the Acupuncture Licensure Act, provides for the licensure and regulation of the practice of acupuncture by the Acupuncture Board. Existing law authorizes the board to appoint an executive officer. Existing law repeals these provisions on January 1, 2013. Under existing law, boards scheduled for repeal are required to be evaluated by the Joint Sunset Review Committee.

This bill would extend the operation of these provisions until January 1, 2015. The bill would instead specify that the board would be subject to review by the appropriate policy committees of the Legislature.

Existing law requires the board, on or before January 1, 2004, to establish standards for the approval of schools and colleges offering education and training in the practice of an acupuncturist. Under existing law, within 3 years of initial approval by the board, each program approved by the board is required to receive full institutional approval by the Bureau for Private Postsecondary Education, which is responsible for, among other things,

providing approval to operate private postsecondary institutions according to specified minimum operating standards.

This bill would provide the board with ongoing authority to establish those standards. The bill would also update references to provisions providing for the approval by the bureau to operate private postsecondary institutions.

(11) Existing law provides for the licensure and regulation of court reporters by the Court Reporters Board of California within the Department of Consumer Affairs. Existing law authorizes this board to appoint an executive officer and committees as necessary. Existing law repeals these provisions on January 1, 2013.

This bill would extend the operation of these provisions until January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.

Existing law requires, until January 1, 2013, certain fees and revenues collected by the board to be deposited into the Transcript Reimbursement Fund to be available to provide reimbursement for the cost of providing shorthand reporting services to low-income litigants in civil cases. Existing law authorizes, until January 1, 2013, low-income persons appearing pro se to apply for funds from the Transcript Reimbursement Fund, subject to specified requirements and limitations. Existing law requires the board, until January 1, 2013, to publicize the availability of the fund to prospective applicants. Existing law requires the unencumbered funds remaining in the Transcript Reimbursement Fund as of January 1, 2013, to be transferred to the Court Reporters' Fund.

This bill would extend the operation of these provisions until January 1, 2017, and would make a technical change to these provisions. By extending the operation of the Transcript Reimbursement Fund, which is a continuously appropriated fund, the bill would make an appropriation.

(12) Existing law, the Electronic and Appliance Repair Dealer Registration Law, provides for the registration and regulation of electronic and appliance service dealers and service contractors by the Bureau of Electronic and Appliance Repair, Home Furnishings, and Thermal Insulation within the Department of Consumer Affairs and makes a failure to comply with its provisions a crime. Existing law, until January 1, 2013, requires a service contractor to pay specified fees to the bureau, including a registration fee and a registration renewal fee. Existing law, until January 1, 2013, requires the Director of Consumer Affairs to gather evidence of violations of the Electronic and Appliance Repair Dealer Registration Law, and any of its regulations, by a service contractor or by any employee, partner, officer, or member of any service contractor. Existing law, until January 1, 2013, requires a service contractor to maintain specified records to be open for inspection by the director and other law enforcement officials. Existing law, until January 1, 2013, also provides for the revocation of the registration of a service contractor by the director and for the superior court to issue a restraining order or injunction against a service contractor who violates these provisions.

This bill would extend the operation of these and other related provisions to January 1, 2015. By extending the operation of certain of these provisions, the violation of which is a crime, this bill would impose a state-mandated local program.

(13) Existing law, until January 1, 2013, establishes the Health Quality Enforcement Section within the Department of Justice for the purpose of investigating and prosecuting proceedings against licensees and applicants within the jurisdiction of the Medical Board of California, the California Board of Podiatric Medicine, the Board of Psychology, or any committee under the jurisdiction of the Medical Board of California. Existing law, until January 1, 2013, requires all complaints against licensees of these boards to be made available to the Health Quality Enforcement Section.

This bill would extend the operation of these provisions until January 1, 2014.

(14) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 800 of the Business and Professions Code is amended to read:

800. (a) The Medical Board of California, the Board of Psychology, the Dental Board of California, the Osteopathic Medical Board of California, the State Board of Chiropractic Examiners, the Board of Registered Nursing, the Board of Vocational Nursing and Psychiatric Technicians, the State Board of Optometry, the Veterinary Medical Board, the Board of Behavioral Sciences, the Physical Therapy Board of California, the California State Board of Pharmacy, the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board, the California Board of Occupational Therapy, the Acupuncture Board, and the Physician Assistant Board shall each separately create and maintain a central file of the names of all persons who hold a license, certificate, or similar authority from that board. Each central file shall be created and maintained to provide an individual historical record for each licensee with respect to the following information:

(1) Any conviction of a crime in this or any other state that constitutes unprofessional conduct pursuant to the reporting requirements of Section 803.

(2) Any judgment or settlement requiring the licensee or his or her insurer to pay any amount of damages in excess of three thousand dollars ($3,000) for any claim that injury or death was proximately caused by the licensee's negligence, error or omission in practice, or by rendering unauthorized

professional services, pursuant to the reporting requirements of Section 801 or 802.

(3) Any public complaints for which provision is made pursuant to subdivision (b).

(4) Disciplinary information reported pursuant to Section 805, including any additional exculpatory or explanatory statements submitted by the licentiate pursuant to subdivision (f) of Section 805. If a court finds, in a final judgment, that the peer review resulting in the 805 report was conducted in bad faith and the licensee who is the subject of the report notifies the board of that finding, the board shall include that finding in the central file. For purposes of this paragraph, "peer review" has the same meaning as defined in Section 805.

(5) Information reported pursuant to Section 805.01, including any explanatory or exculpatory information submitted by the licensee pursuant to subdivision (b) of that section.

(b) Each board shall prescribe and promulgate forms on which members of the public and other licensees or certificate holders may file written complaints to the board alleging any act of misconduct in, or connected with, the performance of professional services by the licensee.

If a board, or division thereof, a committee, or a panel has failed to act upon a complaint or report within five years, or has found that the complaint or report is without merit, the central file shall be purged of information relating to the complaint or report.

Notwithstanding this subdivision, the Board of Psychology, the Board of Behavioral Sciences, and the Respiratory Care Board of California shall maintain complaints or reports as long as each board deems necessary.

(c) The contents of any central file that are not public records under any other provision of law shall be confidential except that the licensee involved, or his or her counsel or representative, shall have the right to inspect and have copies made of his or her complete file except for the provision that may disclose the identity of an information source. For the purposes of this section, a board may protect an information source by providing a copy of the material with only those deletions necessary to protect the identity of the source or by providing a comprehensive summary of the substance of the material. Whichever method is used, the board shall ensure that full disclosure is made to the subject of any personal information that could reasonably in any way reflect or convey anything detrimental, disparaging, or threatening to a licensee's reputation, rights, benefits, privileges, or qualifications, or be used by a board to make a determination that would affect a licensee's rights, benefits, privileges, or qualifications. The information required to be disclosed pursuant to Section 803.1 shall not be considered among the contents of a central file for the purposes of this subdivision.

The licensee may, but is not required to, submit any additional exculpatory or explanatory statement or other information that the board shall include in the central file.

Each board may permit any law enforcement or regulatory agency when required for an investigation of unlawful activity or for licensing, certification, or regulatory purposes to inspect and have copies made of that licensee's file, unless the disclosure is otherwise prohibited by law.

These disclosures shall effect no change in the confidential status of these records.

SEC. 2. Section 801.01 of the Business and Professions Code is amended to read:

801.01. The Legislature finds and declares that the filing of reports with the applicable state agencies required under this section is essential for the protection of the public. It is the intent of the Legislature that the reporting requirements set forth in this section be interpreted broadly in order to expand reporting obligations.

(a) A complete report shall be sent to the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, or the Physician Assistant Board with respect to a licensee of the board as to the following:

(1) A settlement over thirty thousand dollars ($30,000) or arbitration award of any amount or a civil judgment of any amount, whether or not vacated by a settlement after entry of the judgment, that was not reversed on appeal, of a claim or action for damages for death or personal injury caused by the licensee's alleged negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services.

(2) A settlement over thirty thousand dollars ($30,000), if the settlement is based on the licensee's alleged negligence, error, or omission in practice, or on the licensee's rendering of unauthorized professional services, and a party to the settlement is a corporation, medical group, partnership, or other corporate entity in which the licensee has an ownership interest or that employs or contracts with the licensee.

(b) The report shall be sent by the following:

(1) The insurer providing professional liability insurance to the licensee.

(2) The licensee, or his or her counsel, if the licensee does not possess professional liability insurance.

(3) A state or local governmental agency that self-insures the licensee. For purposes of this section, "state governmental agency" includes, but is not limited to, the University of California.

(c) The entity, person, or licensee obligated to report pursuant to subdivision (b) shall send the complete report if the judgment, settlement agreement, or arbitration award is entered against or paid by the employer of the licensee and not entered against or paid by the licensee. "Employer," as used in this paragraph, means a professional corporation, a group practice, a health care facility or clinic licensed or exempt from licensure under the Health and Safety Code, a licensed health care service plan, a medical care foundation, an educational institution, a professional institution, a professional school or college, a general law corporation, a public entity, or a nonprofit organization that employs, retains, or contracts with a licensee referred to in this section. Nothing in this paragraph shall be construed to

authorize the employment of, or contracting with, any licensee in violation of Section 2400.

(d) The report shall be sent to the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, or the Physician Assistant Board as appropriate, within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto, within 30 days after service of the arbitration award on the parties, or within 30 days after the date of entry of the civil judgment.

(e) The entity, person, or licensee required to report under subdivision (b) shall notify the claimant or his or her counsel, if he or she is represented by counsel, that the report has been sent to the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, or the Physician Assistant Board. If the claimant or his or her counsel has not received this notice within 45 days after the settlement was reduced to writing and signed by all of the parties or the arbitration award was served on the parties or the date of entry of the civil judgment, the claimant or the claimant's counsel shall make the report to the appropriate board.

(f) Failure to substantially comply with this section is a public offense punishable by a fine of not less than five hundred dollars ($500) and not more than five thousand dollars ($5,000).

(g) (1) The Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the Physician Assistant Board may develop a prescribed form for the report.

(2) The report shall be deemed complete only if it includes the following information:

(A) The name and last known business and residential addresses of every plaintiff or claimant involved in the matter, whether or not the person received an award under the settlement, arbitration, or judgment.

(B) The name and last known business and residential addresses of every licensee who was alleged to have acted improperly, whether or not that person was a named defendant in the action and whether or not that person was required to pay any damages pursuant to the settlement, arbitration award, or judgment.

(C) The name, address, and principal place of business of every insurer providing professional liability insurance to any person described in subparagraph (B), and the insured's policy number.

(D) The name of the court in which the action or any part of the action was filed, and the date of filing and case number of each action.

(E) A description or summary of the facts of each claim, charge, or allegation, including the date of occurrence and the licensee's role in the care or professional services provided to the patient with respect to those services at issue in the claim or action.

(F) The name and last known business address of each attorney who represented a party in the settlement, arbitration, or civil action, including the name of the client he or she represented.

(G) The amount of the judgment, the date of its entry, and a copy of the judgment; the amount of the arbitration award, the date of its service on the parties, and a copy of the award document; or the amount of the settlement and the date it was reduced to writing and signed by all parties. If an otherwise reportable settlement is entered into after a reportable judgment or arbitration award is issued, the report shall include both the settlement and a copy of the judgment or award.

(H) The specialty or subspecialty of the licensee who was the subject of the claim or action.

(I) Any other information the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, or the Physician Assistant Board may, by regulation, require.

(3) Every professional liability insurer, self-insured governmental agency, or licensee or his or her counsel that makes a report under this section and has received a copy of any written or electronic patient medical or hospital records prepared by the treating physician and surgeon, podiatrist, or physician assistant, or the staff of the treating physician and surgeon, podiatrist, or hospital, describing the medical condition, history, care, or treatment of the person whose death or injury is the subject of the report, or a copy of any deposition in the matter that discusses the care, treatment, or medical condition of the person, shall include with the report, copies of the records and depositions, subject to reasonable costs to be paid by the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, or the Physician Assistant Board. If confidentiality is required by court order and, as a result, the reporter is unable to provide the records and depositions, documentation to that effect shall accompany the original report. The applicable board may, upon prior notification of the parties to the action, petition the appropriate court for modification of any protective order to permit disclosure to the board. A professional liability insurer, self-insured governmental agency, or licensee or his or her counsel shall maintain the records and depositions referred to in this paragraph for at least one year from the date of filing of the report required by this section.

(h) If the board, within 60 days of its receipt of a report filed under this section, notifies a person named in the report, that person shall maintain for the period of three years from the date of filing of the report any records he or she has as to the matter in question and shall make those records available upon request to the board to which the report was sent.

(i) Notwithstanding any other provision of law, no insurer shall enter into a settlement without the written consent of the insured, except that this prohibition shall not void any settlement entered into without that written consent. The requirement of written consent shall only be waived by both the insured and the insurer.

(j) (1) A state or local governmental agency that self-insures licensees shall, prior to sending a report pursuant to this section, do all of the following with respect to each licensee who will be identified in the report:

(A) Before deciding that a licensee will be identified, provide written notice to the licensee that the agency intends to submit a report in which the licensee may be identified, based on his or her role in the care or professional services provided to the patient that were at issue in the claim or action. This notice shall describe the reasons for notifying the licensee. The agency shall include with this notice a reasonable opportunity for the licensee to review a copy of records to be used by the agency in deciding whether to identify the licensee in the report.

(B) Provide the licensee with a reasonable opportunity to provide a written response to the agency and written materials in support of the licensee's position. If the licensee is identified in the report, the agency shall include this response and materials in the report submitted to a board under this section if requested by the licensee.

(C) At least 10 days prior to the expiration of the 30-day reporting requirement under subdivision (d), provide the licensee with the opportunity to present arguments to the body that will make the final decision or to that body's designee. The body shall review the care or professional services provided to the patient with respect to those services at issue in the claim or action and determine the licensee or licensees to be identified in the report and the amount of the settlement to be apportioned to the licensee.

(2) Nothing in this subdivision shall be construed to modify either the content of a report required under this section or the timeframe for filing that report.

(k) For purposes of this section, "licensee" means a licensee of the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, or the Physician Assistant Board.

SEC. 3. Section 802.1 of the Business and Professions Code is amended to read:

802.1. (a) (1) A physician and surgeon, osteopathic physician and surgeon, a doctor of podiatric medicine, and a physician assistant shall report either of the following to the entity that issued his or her license:

(A) The bringing of an indictment or information charging a felony against the licensee.

(B) The conviction of the licensee, including any verdict of guilty, or plea of guilty or no contest, of any felony or misdemeanor.

(2) The report required by this subdivision shall be made in writing within 30 days of the date of the bringing of the indictment or information or of the conviction.

(b) Failure to make a report required by this section shall be a public offense punishable by a fine not to exceed five thousand dollars ($5,000).

SEC. 4. Section 802.5 of the Business and Professions Code is amended to read:

802.5. (a) When a coroner receives information that is based on findings that were reached by, or documented and approved by a board-certified or board-eligible pathologist indicating that a death may be the result of a physician and surgeon's, podiatrist's, or physician assistant's gross negligence or incompetence, a report shall be filed with the Medical Board

of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, or the Physician Assistant Board. The initial report shall include the name of the decedent, date and place of death, attending physicians or podiatrists, and all other relevant information available. The initial report shall be followed, within 90 days, by copies of the coroner's report, autopsy protocol, and all other relevant information.

(b) The report required by this section shall be confidential. No coroner, physician and surgeon, or medical examiner, nor any authorized agent, shall be liable for damages in any civil action as a result of his or her acting in compliance with this section. No board-certified or board-eligible pathologist, nor any authorized agent, shall be liable for damages in any civil action as a result of his or her providing information under subdivision (a).

SEC. 5. Section 803 of the Business and Professions Code is amended to read:

803. (a) Except as provided in subdivision (b), within 10 days after a judgment by a court of this state that a person who holds a license, certificate, or other similar authority from the Board of Behavioral Sciences or from an agency mentioned in subdivision (a) of Section 800 (except a person licensed pursuant to Chapter 3 (commencing with Section 1200)) has committed a crime, or is liable for any death or personal injury resulting in a judgment for an amount in excess of thirty thousand dollars ($30,000) caused by his or her negligence, error or omission in practice, or his or her rendering unauthorized professional services, the clerk of the court that rendered the judgment shall report that fact to the agency that issued the license, certificate, or other similar authority.

(b) For purposes of a physician and surgeon, osteopathic physician and surgeon, doctor of podiatric medicine, or physician assistant, who is liable for any death or personal injury resulting in a judgment of any amount caused by his or her negligence, error or omission in practice, or his or her rendering unauthorized professional services, the clerk of the court that rendered the judgment shall report that fact to the agency that issued the license.

SEC. 6. Section 803.1 of the Business and Professions Code is amended to read:

803.1. (a) Notwithstanding any other provision of law, the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the Physician Assistant Board shall disclose to an inquiring member of the public information regarding any enforcement actions taken against a licensee, including a former licensee, by the board or by another state or jurisdiction, including all of the following:

(1) Temporary restraining orders issued.

(2) Interim suspension orders issued.

(3) Revocations, suspensions, probations, or limitations on practice ordered by the board, including those made part of a probationary order or stipulated agreement.

(4) Public letters of reprimand issued.

(5) Infractions, citations, or fines imposed.

(b) Notwithstanding any other provision of law, in addition to the information provided in subdivision (a), the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the Physician Assistant Board shall disclose to an inquiring member of the public all of the following:

(1) Civil judgments in any amount, whether or not vacated by a settlement after entry of the judgment, that were not reversed on appeal and arbitration awards in any amount of a claim or action for damages for death or personal injury caused by the physician and surgeon's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services.

(2) (A) All settlements in the possession, custody, or control of the board shall be disclosed for a licensee in the low-risk category if there are three or more settlements for that licensee within the last 10 years, except for settlements by a licensee regardless of the amount paid where (i) the settlement is made as a part of the settlement of a class claim, (ii) the licensee paid in settlement of the class claim the same amount as the other licensees in the same class or similarly situated licensees in the same class, and (iii) the settlement was paid in the context of a case where the complaint that alleged class liability on behalf of the licensee also alleged a products liability class action cause of action. All settlements in the possession, custody, or control of the board shall be disclosed for a licensee in the high-risk category if there are four or more settlements for that licensee within the last 10 years except for settlements by a licensee regardless of the amount paid where (i) the settlement is made as a part of the settlement of a class claim, (ii) the licensee paid in settlement of the class claim the same amount as the other licensees in the same class or similarly situated licensees in the same class, and (iii) the settlement was paid in the context of a case where the complaint that alleged class liability on behalf of the licensee also alleged a products liability class action cause of action. Classification of a licensee in either a "high-risk category" or a "low-risk category" depends upon the specialty or subspecialty practiced by the licensee and the designation assigned to that specialty or subspecialty by the Medical Board of California, as described in subdivision (f). For the purposes of this paragraph, "settlement" means a settlement of an action described in paragraph (1) entered into by the licensee on or after January 1, 2003, in an amount of thirty thousand dollars ($30,000) or more.

(B) The board shall not disclose the actual dollar amount of a settlement but shall put the number and amount of the settlement in context by doing the following:

(i) Comparing the settlement amount to the experience of other licensees within the same specialty or subspecialty, indicating if it is below average, average, or above average for the most recent 10-year period.

(ii) Reporting the number of years the licensee has been in practice.

(iii) Reporting the total number of licensees in that specialty or subspecialty, the number of those who have entered into a settlement

agreement, and the percentage that number represents of the total number of licensees in the specialty or subspecialty.

(3) Current American Board of Medical Specialties certification or board equivalent as certified by the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine.

(4) Approved postgraduate training.

(5) Status of the license of a licensee. By January 1, 2004, the Medical Board of California, the Osteopathic Medical Board of California, and the California Board of Podiatric Medicine shall adopt regulations defining the status of a licensee. The board shall employ this definition when disclosing the status of a licensee pursuant to Section 2027.

(6) Any summaries of hospital disciplinary actions that result in the termination or revocation of a licensee's staff privileges for medical disciplinary cause or reason, unless a court finds, in a final judgment, that the peer review resulting in the disciplinary action was conducted in bad faith and the licensee notifies the board of that finding. In addition, any exculpatory or explanatory statements submitted by the licentiate electronically pursuant to subdivision (f) of that section shall be disclosed. For purposes of this paragraph, "peer review" has the same meaning as defined in Section 805.

(c) Notwithstanding any other provision of law, the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the Physician Assistant Board shall disclose to an inquiring member of the public information received regarding felony convictions of a physician and surgeon or doctor of podiatric medicine.

(d) The Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the Physician Assistant Board may formulate appropriate disclaimers or explanatory statements to be included with any information released, and may by regulation establish categories of information that need not be disclosed to an inquiring member of the public because that information is unreliable or not sufficiently related to the licensee's professional practice. The Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the Physician Assistant Board shall include the following statement when disclosing information concerning a settlement:

"Some studies have shown that there is no significant correlation between malpractice history and a doctor's competence. At the same time, the State of California believes that consumers should have access to malpractice information. In these profiles, the State of California has given you information about both the malpractice settlement history for the doctor's specialty and the doctor's history of settlement payments only if in the last 10 years, the doctor, if in a low-risk specialty, has three or more settlements or the doctor, if in a high-risk specialty, has four or more settlements. The State of California has excluded some class action lawsuits because those cases are commonly related to systems issues such as product liability, rather

than questions of individual professional competence and because they are brought on a class basis where the economic incentive for settlement is great. The State of California has placed payment amounts into three statistical categories: below average, average, and above average compared to others in the doctor's specialty. To make the best health care decisions, you should view this information in perspective. You could miss an opportunity for high-quality care by selecting a doctor based solely on malpractice history.

When considering malpractice data, please keep in mind:

Malpractice histories tend to vary by specialty. Some specialties are more likely than others to be the subject of litigation. This report compares doctors only to the members of their specialty, not to all doctors, in order to make an individual doctor's history more meaningful.

This report reflects data only for settlements made on or after January 1, 2003. Moreover, it includes information concerning those settlements for a 10-year period only. Therefore, you should know that a doctor may have made settlements in the 10 years immediately preceding January 1, 2003, that are not included in this report. After January 1, 2013, for doctors practicing less than 10 years, the data covers their total years of practice. You should take into account the effective date of settlement disclosure as well as how long the doctor has been in practice when considering malpractice averages.

The incident causing the malpractice claim may have happened years before a payment is finally made. Sometimes, it takes a long time for a malpractice lawsuit to settle. Some doctors work primarily with high-risk patients. These doctors may have malpractice settlement histories that are higher than average because they specialize in cases or patients who are at very high risk for problems.

Settlement of a claim may occur for a variety of reasons that do not necessarily reflect negatively on the professional competence or conduct of the doctor. A payment in settlement of a medical malpractice action or claim should not be construed as creating a presumption that medical malpractice has occurred.

You may wish to discuss information in this report and the general issue of malpractice with your doctor."

(e) The Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the Physician Assistant Board shall, by regulation, develop standard terminology that accurately describes the different types of disciplinary filings and actions to take against a licensee as described in paragraphs (1) to (5), inclusive, of subdivision (a). In providing the public with information about a licensee via the Internet pursuant to Section 2027, the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the Physician Assistant Board shall not use the terms "enforcement," "discipline," or similar language implying a sanction

unless the physician and surgeon has been the subject of one of the actions described in paragraphs (1) to (5), inclusive, of subdivision (a).

(f) The Medical Board of California shall adopt regulations no later than July 1, 2003, designating each specialty and subspecialty practice area as either high risk or low risk. In promulgating these regulations, the board shall consult with commercial underwriters of medical malpractice insurance companies, health care systems that self-insure physicians and surgeons, and representatives of the California medical specialty societies. The board shall utilize the carriers' statewide data to establish the two risk categories and the averages required by subparagraph (B) of paragraph (2) of subdivision (b). Prior to issuing regulations, the board shall convene public meetings with the medical malpractice carriers, self-insurers, and specialty representatives.

(g) The Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, the Physician Assistant Board shall provide each licensee, including a former licensee under subdivision (a), with a copy of the text of any proposed public disclosure authorized by this section prior to release of the disclosure to the public. The licensee shall have 10 working days from the date the board provides the copy of the proposed public disclosure to propose corrections of factual inaccuracies. Nothing in this section shall prevent the board from disclosing information to the public prior to the expiration of the 10-day period.

(h) Pursuant to subparagraph (A) of paragraph (2) of subdivision (b), the specialty or subspecialty information required by this section shall group physicians by specialty board recognized pursuant to paragraph (5) of subdivision (h) of Section 651 unless a different grouping would be more valid and the board, in its statement of reasons for its regulations, explains why the validity of the grouping would be more valid.

SEC. 7. Section 803.5 of the Business and Professions Code is amended to read:

803.5. (a) The district attorney, city attorney, or other prosecuting agency shall notify the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, the State Board of Chiropractic Examiners, the Physician Assistant Board, or other appropriate allied health board, and the clerk of the court in which the charges have been filed, of any filings against a licensee of that board charging a felony immediately upon obtaining information that the defendant is a licensee of the board. The notice shall identify the licensee and describe the crimes charged and the facts alleged. The prosecuting agency shall also notify the clerk of the court in which the action is pending that the defendant is a licensee, and the clerk shall record prominently in the file that the defendant holds a license from one of the boards described above.

(b) The clerk of the court in which a licensee of one of the boards is convicted of a crime shall, within 48 hours after the conviction, transmit a certified copy of the record of conviction to the applicable board.

SEC. 8. Section 803.6 of the Business and Professions Code is amended to read:

803.6. (a) The clerk of the court shall transmit any felony preliminary hearing transcript concerning a defendant licensee to the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, the Physician Assistant Board, or other appropriate allied health board, as applicable, where the total length of the transcript is under 800 pages and shall notify the appropriate board of any proceeding where the transcript exceeds that length.

(b) In any case where a probation report on a licensee is prepared for a court pursuant to Section 1203 of the Penal Code, a copy of that report shall be transmitted by the probation officer to the board.

SEC. 9. Section 805 of the Business and Professions Code is amended to read:

805. (a) As used in this section, the following terms have the following definitions:

(1) (A) "Peer review" means both of the following:

(i) A process in which a peer review body reviews the basic qualifications, staff privileges, employment, medical outcomes, or professional conduct of licentiates to make recommendations for quality improvement and education, if necessary, in order to do either or both of the following:

(I) Determine whether a licentiate may practice or continue to practice in a health care facility, clinic, or other setting providing medical services, and, if so, to determine the parameters of that practice.

(II) Assess and improve the quality of care rendered in a health care facility, clinic, or other setting providing medical services.

(ii) Any other activities of a peer review body as specified in subparagraph (B).

(B) "Peer review body" includes:

(i) A medical or professional staff of any health care facility or clinic licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code or of a facility certified to participate in the federal Medicare program as an ambulatory surgical center.

(ii) A health care service plan licensed under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or a disability insurer that contracts with licentiates to provide services at alternative rates of payment pursuant to Section 10133 of the Insurance Code.

(iii) Any medical, psychological, marriage and family therapy, social work, professional clinical counselor, dental, or podiatric professional society having as members at least 25 percent of the eligible licentiates in the area in which it functions (which must include at least one county), which is not organized for profit and which has been determined to be exempt from taxes pursuant to Section 23701 of the Revenue and Taxation Code.

(iv) A committee organized by any entity consisting of or employing more than 25 licentiates of the same class that functions for the purpose of

reviewing the quality of professional care provided by members or employees of that entity.

(2) "Licentiate" means a physician and surgeon, doctor of podiatric medicine, clinical psychologist, marriage and family therapist, clinical social worker, professional clinical counselor, dentist, or physician assistant. "Licentiate" also includes a person authorized to practice medicine pursuant to Section 2113 or 2168.

(3) "Agency" means the relevant state licensing agency having regulatory jurisdiction over the licentiates listed in paragraph (2).

(4) "Staff privileges" means any arrangement under which a licentiate is allowed to practice in or provide care for patients in a health facility. Those arrangements shall include, but are not limited to, full staff privileges, active staff privileges, limited staff privileges, auxiliary staff privileges, provisional staff privileges, temporary staff privileges, courtesy staff privileges, locum tenens arrangements, and contractual arrangements to provide professional services, including, but not limited to, arrangements to provide outpatient services.

(5) "Denial or termination of staff privileges, membership, or employment" includes failure or refusal to renew a contract or to renew, extend, or reestablish any staff privileges, if the action is based on medical disciplinary cause or reason.

(6) "Medical disciplinary cause or reason" means that aspect of a licentiate's competence or professional conduct that is reasonably likely to be detrimental to patient safety or to the delivery of patient care.

(7) "805 report" means the written report required under subdivision (b).

(b) The chief of staff of a medical or professional staff or other chief executive officer, medical director, or administrator of any peer review body and the chief executive officer or administrator of any licensed health care facility or clinic shall file an 805 report with the relevant agency within 15 days after the effective date on which any of the following occur as a result of an action of a peer review body:

(1) A licentiate's application for staff privileges or membership is denied or rejected for a medical disciplinary cause or reason.

(2) A licentiate's membership, staff privileges, or employment is terminated or revoked for a medical disciplinary cause or reason.

(3) Restrictions are imposed, or voluntarily accepted, on staff privileges, membership, or employment for a cumulative total of 30 days or more for any 12-month period, for a medical disciplinary cause or reason.

(c) If a licentiate takes any action listed in paragraph (1), (2), or (3) after receiving notice of a pending investigation initiated for a medical disciplinary cause or reason or after receiving notice that his or her application for membership or staff privileges is denied or will be denied for a medical disciplinary cause or reason, the chief of staff of a medical or professional staff or other chief executive officer, medical director, or administrator of any peer review body and the chief executive officer or administrator of any licensed health care facility or clinic where the licentiate is employed or has staff privileges or membership or where the licentiate applied for

staff privileges or membership, or sought the renewal thereof, shall file an 805 report with the relevant agency within 15 days after the licentiate takes the action.

(1) Resigns or takes a leave of absence from membership, staff privileges, or employment.

(2) Withdraws or abandons his or her application for staff privileges or membership.

(3) Withdraws or abandons his or her request for renewal of staff privileges or membership.

(d) For purposes of filing an 805 report, the signature of at least one of the individuals indicated in subdivision (b) or (c) on the completed form shall constitute compliance with the requirement to file the report.

(e) An 805 report shall also be filed within 15 days following the imposition of summary suspension of staff privileges, membership, or employment, if the summary suspension remains in effect for a period in excess of 14 days.

(f) A copy of the 805 report, and a notice advising the licentiate of his or her right to submit additional statements or other information, electronically or otherwise, pursuant to Section 800, shall be sent by the peer review body to the licentiate named in the report. The notice shall also advise the licentiate that information submitted electronically will be publicly disclosed to those who request the information.

The information to be reported in an 805 report shall include the name and license number of the licentiate involved, a description of the facts and circumstances of the medical disciplinary cause or reason, and any other relevant information deemed appropriate by the reporter.

A supplemental report shall also be made within 30 days following the date the licentiate is deemed to have satisfied any terms, conditions, or sanctions imposed as disciplinary action by the reporting peer review body. In performing its dissemination functions required by Section 805.5, the agency shall include a copy of a supplemental report, if any, whenever it furnishes a copy of the original 805 report.

If another peer review body is required to file an 805 report, a health care service plan is not required to file a separate report with respect to action attributable to the same medical disciplinary cause or reason. If the Medical Board of California or a licensing agency of another state revokes or suspends, without a stay, the license of a physician and surgeon, a peer review body is not required to file an 805 report when it takes an action as a result of the revocation or suspension.

(g) The reporting required by this section shall not act as a waiver of confidentiality of medical records and committee reports. The information reported or disclosed shall be kept confidential except as provided in subdivision (c) of Section 800 and Sections 803.1 and 2027, provided that a copy of the report containing the information required by this section may be disclosed as required by Section 805.5 with respect to reports received on or after January 1, 1976.

(h) The Medical Board of California, the Osteopathic Medical Board of California, and the Dental Board of California shall disclose reports as required by Section 805.5.

(i) An 805 report shall be maintained electronically by an agency for dissemination purposes for a period of three years after receipt.

(j) No person shall incur any civil or criminal liability as the result of making any report required by this section.

(k) A willful failure to file an 805 report by any person who is designated or otherwise required by law to file an 805 report is punishable by a fine not to exceed one hundred thousand dollars ($100,000) per violation. The fine may be imposed in any civil or administrative action or proceeding brought by or on behalf of any agency having regulatory jurisdiction over the person regarding whom the report was or should have been filed. If the person who is designated or otherwise required to file an 805 report is a licensed physician and surgeon, the action or proceeding shall be brought by the Medical Board of California. The fine shall be paid to that agency but not expended until appropriated by the Legislature. A violation of this subdivision may constitute unprofessional conduct by the licentiate. A person who is alleged to have violated this subdivision may assert any defense available at law. As used in this subdivision, "willful" means a voluntary and intentional violation of a known legal duty.

(*l*) Except as otherwise provided in subdivision (k), any failure by the administrator of any peer review body, the chief executive officer or administrator of any health care facility, or any person who is designated or otherwise required by law to file an 805 report, shall be punishable by a fine that under no circumstances shall exceed fifty thousand dollars ($50,000) per violation. The fine may be imposed in any civil or administrative action or proceeding brought by or on behalf of any agency having regulatory jurisdiction over the person regarding whom the report was or should have been filed. If the person who is designated or otherwise required to file an 805 report is a licensed physician and surgeon, the action or proceeding shall be brought by the Medical Board of California. The fine shall be paid to that agency but not expended until appropriated by the Legislature. The amount of the fine imposed, not exceeding fifty thousand dollars ($50,000) per violation, shall be proportional to the severity of the failure to report and shall differ based upon written findings, including whether the failure to file caused harm to a patient or created a risk to patient safety; whether the administrator of any peer review body, the chief executive officer or administrator of any health care facility, or any person who is designated or otherwise required by law to file an 805 report exercised due diligence despite the failure to file or whether they knew or should have known that an 805 report would not be filed; and whether there has been a prior failure to file an 805 report. The amount of the fine imposed may also differ based on whether a health care facility is a small or rural hospital as defined in Section 124840 of the Health and Safety Code.

(m) A health care service plan licensed under Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or a

disability insurer that negotiates and enters into a contract with licentiates to provide services at alternative rates of payment pursuant to Section 10133 of the Insurance Code, when determining participation with the plan or insurer, shall evaluate, on a case-by-case basis, licentiates who are the subject of an 805 report, and not automatically exclude or deselect these licentiates.

SEC. 10. Section 2006 of the Business and Professions Code is amended to read:

2006. (a) Any reference in this chapter to an investigation by the board shall be deemed to refer to a joint investigation conducted by employees of the Department of Justice and the board under the vertical enforcement and prosecution model, as specified in Section 12529.6 of the Government Code.

(b) This section shall remain in effect only until January 1, 2014, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2014, deletes or extends that date.

SEC. 11. Section 2335 of the Business and Professions Code is amended to read:

2335. (a) All proposed decisions and interim orders of the Medical Quality Hearing Panel designated in Section 11371 of the Government Code shall be transmitted to the executive director of the board, or the executive director of the California Board of Podiatric Medicine as to the licensees of that board, within 48 hours of filing.

(b) All interim orders shall be final when filed.

(c) A proposed decision shall be acted upon by the board or by any panel appointed pursuant to Section 2008 or by the California Board of Podiatric Medicine, as the case may be, in accordance with Section 11517 of the Government Code, except that all of the following shall apply to proceedings against licensees under this chapter:

(1) When considering a proposed decision, the board or panel and the California Board of Podiatric Medicine shall give great weight to the findings of fact of the administrative law judge, except to the extent those findings of fact are controverted by new evidence.

(2) The board's staff or the staff of the California Board of Podiatric Medicine shall poll the members of the board or panel or of the California Board of Podiatric Medicine by written mail ballot concerning the proposed decision. The mail ballot shall be sent within 10 calendar days of receipt of the proposed decision, and shall poll each member on whether the member votes to approve the decision, to approve the decision with an altered penalty, to refer the case back to the administrative law judge for the taking of additional evidence, to defer final decision pending discussion of the case by the panel or board as a whole, or to nonadopt the decision. No party to the proceeding, including employees of the agency that filed the accusation, and no person who has a direct or indirect interest in the outcome of the proceeding or who presided at a previous stage of the decision, may communicate directly or indirectly, upon the merits of a contested matter while the proceeding is pending, with any member of the panel or board, without notice and opportunity for all parties to participate in the communication. The votes of a majority of the board or of the panel, and a

(commencing with Section 13400) of Division 3 of Title 1 of the Corporations Code is the board.

SEC. 82. Section 3546 of the Business and Professions Code is amended to read:

3546. The Medical Board of California may adopt and enforce regulations to carry out the purposes and objectives of this article, including regulations requiring (a) that the bylaws of a physician assistant corporation shall include a provision whereby the capital stock of the corporation owned by a disqualified person (as defined in Section 13401 of the Corporations Code), or a deceased person, shall be sold to the corporation or to the remaining shareholders of the corporation within the time as the regulations may provide, and (b) that a physician assistant corporation shall provide adequate security by insurance or otherwise for claims against it by its patients arising out of the rendering of professional services.

SEC. 83. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date. Notwithstanding any other provision of law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 84. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.

SEC. 85. Section 4928 of the Business and Professions Code is amended to read:

4928. The Acupuncture Board, which consists of seven members, shall enforce and administer this chapter.

This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

Notwithstanding any other provision of law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 86. Section 4934 of the Business and Professions Code is amended to read:

4934. (a) The board, by and with the approval of the director, may employ personnel necessary for the administration of this chapter, and the board, by and with the approval of the director, may appoint an executive officer who is exempt from the provisions of the State Civil Service Act (Part 2 (commencing with Section 18500) of Division 5 of Title 2 of the Government Code).

(b) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

Senate Bill No. 1301

CHAPTER 455

An act to add Section 4064.5 to the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 22, 2012. Filed with Secretary of State September 22, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1301, Hernandez. Prescription drugs: 90-day supply.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy. Existing law prohibits a person from furnishing a dangerous drug except upon the prescription of specified practitioners, except as specified. Existing law authorizes a pharmacist filling a prescription order for a drug product to substitute a generic drug product or a drug product with a different form of medication having the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product, subject to specified requirements. Existing law also authorizes a pharmacist to refill a prescription for a dangerous drug without the prescriber's authorization under specified circumstances.

This bill would authorize a pharmacist to dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription if the patient has completed an initial 30-day supply of the drug, except as specified, the pharmacist is exercising his or her professional judgment, the pharmacist dispenses no more than the total amount prescribed, including refills, and the prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary. The bill would prohibit a pharmacist from dispensing a dangerous drug pursuant to these provisions if the prescriber indicates "No change to quantity" or words of similar meaning, as specified. The bill would require a pharmacist dispensing an increased supply of a dangerous drug pursuant to these provisions to notify the prescriber of the increase in the quantity of dosage units dispensed. The bill would provide that these provisions are not applicable to psychotropic medication or psychotropic drugs, as described.

The people of the State of California do enact as follows:

SECTION 1. Section 4064.5 is added to the Business and Professions Code, to read:

4064.5. (a) A pharmacist may dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if all of the following requirements are satisfied:

(1) The patient has completed an initial 30-day supply of the dangerous drug.

(2) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.

(3) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

(4) The pharmacist is exercising his or her professional judgment.

(b) For purposes of this section, if the prescription continues the same medication as previously dispensed in a 90-day supply, the initial 30-day supply under paragraph (1) of subdivision (a) is not required.

(c) A pharmacist dispensing an increased supply of a dangerous drug pursuant to this section shall notify the prescriber of the increase in the quantity of dosage units dispensed.

(d) In no case shall a pharmacist dispense a greater supply of a dangerous drug pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, “No change to quantity,” or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked “No change to quantity,” provided that the prescriber personally initials the box or checkmark. To indicate that an increased supply shall not be dispensed pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate “No change to quantity,” or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription “No change to quantity.” In either instance, it shall not be required that the prohibition on an increased supply be manually initialed by the prescriber.

(e) This section shall not apply to psychotropic medication or psychotropic drugs as described in subdivision (d) of Section 369.5 of the Welfare and Institutions Code.

(f) Nothing in this section shall be construed to require a health care service plan, health insurer, workers’ compensation insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a dangerous drug in a manner inconsistent with a beneficiary’s plan benefit.

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Senate Bill No. 1329

CHAPTER 709

An act to amend Sections 150200, 150201, 150202, 150204, and 150205 of, and to add Section 150202.5 to, the Health and Safety Code, relating to pharmaceuticals.

[Approved by Governor September 28, 2012. Filed with Secretary of State September 28, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1329, Simitian. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which a pharmacy that is owned by or contracts with the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law requires a county that has established a program to establish procedures to, among other things, ensure proper safety and management of any medications collected and maintained by a participating pharmacy. Existing law authorizes a skilled nursing facility, specified drug manufacturer, or pharmacy wholesaler to donate medications to the program. Existing law requires medication under the program to be dispensed to an eligible patient, destroyed, or returned to a reverse distributor, as specified. Except in cases of noncompliance, bad faith, or gross negligence, existing law prohibits certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program's provisions.

This bill would authorize a county to establish the program by action of the county board of supervisors or by action of a public health officer of the county, as prescribed. This bill would also authorize specified primary care clinics and pharmacies to participate in the program. This bill would require a pharmacy or clinic seeking to participate in the program to inform the county health department in writing of its intent and prohibit the pharmacy or clinic from participating until the county health department has confirmed that it has received this notice. This bill would require participating pharmacies and clinics to disclose specified information to the county health department and require the county board of supervisors or public health officer to make this information available upon request to the California State Board of Pharmacy. This bill would authorize the county board of supervisors, public health officer, and California State Board of Pharmacy to prohibit a pharmacy or clinic from participating in the program, under certain circumstances, and require written notice to be provided to prohibited pharmacies or clinics. This bill would authorize certain licensed

health and care facilities and certain pharmacies, as specified, to donate unused medications to the program, in accordance with prescribed conditions. This bill would also make other conforming changes to those provisions.

The people of the State of California do enact as follows:

SECTION 1. Section 150200 of the Health and Safety Code is amended to read:

150200. It is the intent of the Legislature in enacting this division to authorize the establishment of a voluntary drug repository and distribution program for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. It is also the intent of the Legislature that the health and safety of Californians are protected and promoted through this program, while reducing unnecessary waste at licensed health and care facilities, by allowing those facilities to donate unused and unexpired medications that were never in the hands of a patient or resident and for which no credit or refund to the patient or resident could be received.

SEC. 2. Section 150201 of the Health and Safety Code is amended to read:

150201. For purposes of this division:

(a) "Eligible entity" means all of the following:

(1) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is county owned or that contracts with the county pursuant to this division and is not on probation with the California State Board of Pharmacy.

(2) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and operated by a primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and is not on probation with the California State Board of Pharmacy.

(3) A primary care clinic, as defined in Section 1204, that is licensed by the State Department of Public Health and licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code and is not on probation with the California State Board of Pharmacy.

(b) "Medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.

(c) "Participating entity" means an eligible entity that has received written or electronic documentation from the county health department pursuant to paragraph (3) of subdivision (a) of Section 150204 and that operates a repository and distribution program pursuant to this division.

SEC. 3. Section 150202 of the Health and Safety Code is amended to read:

150202. (a) Notwithstanding any other provision of law, the following health and care facilities may donate centrally stored unused medications under a program established pursuant to this division:

(1) A licensed general acute care hospital, as defined in Section 1250.

(2) A licensed acute psychiatric hospital, as defined in Section 1250.

(3) A licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease.

(4) A licensed intermediate care facility, as defined in Section 1250.

(5) A licensed intermediate care facility/developmentally disabled-habilitative facility, as defined in Section 1250.

(6) A licensed intermediate care facility/developmentally disabled-nursing facility, as defined in Section 1250.

(7) A licensed correctional treatment center, as defined in Section 1250.

(8) A licensed psychiatric health facility, as defined in Section 1250.2.

(9) A licensed chemical dependency recovery hospital, as defined in Section 1250.3.

(10) A licensed residential care facility for the elderly, as defined in Section 1569.2, with 16 or more residents.

(11) An approved mental health rehabilitation center, as described in Section 5675 of the Welfare and Institutions Code.

(b) Medication donated by health and care facilities pursuant to subdivision (a) shall meet the requirements of subdivisions (c) and (d) of Section 150204 and shall be unexpired medication that would have otherwise been destroyed by the facility or another appropriate entity.

(c) Medication eligible for donation by the health and care facilities pursuant to subdivision (a) shall be directly delivered from the dispensing pharmacy, wholesaler or manufacturer, to the health or care facility and subsequently centrally stored. Centrally stored medication that originated from a patient or resident is not eligible for donation under this division.

SEC. 4. Section 150202.5 is added to the Health and Safety Code, to read:

150202.5. Notwithstanding any other law, a pharmacy, licensed in California and not on probation with the California State Board of Pharmacy, whose primary or sole type of pharmacy practice type is limited to a skilled nursing facility, home health care, board and care, or mail order, may donate unused, unexpired medication that meets the requirements of subdivisions (c) and (d) of Section 150204, under a program established pursuant to this division and that meets either of the following requirements:

(a) The medication was received directly from a manufacturer or wholesaler.

(b) The medication was returned from a health facility to the issuing pharmacy, in a manner consistent with state and federal law.

SEC. 5. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county,

as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to subdivision (a) of Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in paragraph (3) of subdivision (a) of Section 150201 shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in Section 150202, shall have been under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

(e) A pharmacist or physician at a participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division. Notwithstanding this paragraph, a participating county-owned pharmacy may transfer eligible donated medication to a participating county-owned pharmacy within another adjacent county that has adopted a program pursuant to this division, if the pharmacies transferring the medication have a written agreement between the entities that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division.

(B) Medication donated under this division shall not be transferred by any participating entity more than once, and after it has been transferred,

shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, and the donation facility from where the medication originated shall be identified on medication packaging or in accompanying documentation. The document shall include a statement that the medication may not be transferred to another participating entity and must be handled pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed or transferred under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) Medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(j) Medication donated to the repository and distribution program shall be segregated from the participating entity's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and distribution program. These records shall be kept separate from the participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(*l*) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating entity shall follow the same procedural drug pedigree requirements for donated

drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

SEC. 6. Section 150205 of the Health and Safety Code is amended to read:

150205. The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:

(a) A prescription drug manufacturer, wholesaler, governmental entity, or participating entity.

(b) A pharmacist or physician who accepts or dispenses prescription drugs.

(c) A licensed health or care facility, as described in Section 150202, or a pharmacy, as described in Section 150202.5.

O

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

September 10, 2012

The Honorable Edmund G. Brown Jr.
Governor
State of California
State Capitol
Sacramento, CA 95814

RE: Senate Bill 1329 (Simitian) - Enrolled

Dear Governor Brown:

The California State Board of Pharmacy respectfully requests your veto of SB 1329 (Simitian) when it comes before you for consideration as an enrolled bill.

Senate Bill 1329 would broaden existing law regarding donations of previously dispensed prescription medication to drug repositories for medically indigent patients. It purports to be a philanthropic expansion of an existing program that will ensure wider provision of medication to medically indigent patients, medication that would be otherwise destroyed.

However, the board believes that several amendments made to the bill -- particularly those made at the end of session -- create overly broad routes that will lead to compromise of the pharmaceutical supply available to all Californians. The recent amendments do not resolve and actually increase the concerns the board addressed with the author's office multiple times since May regarding risks to the California pharmaceutical supply that these new provisions would create. There are other, better ways to provide lifesaving medication to medically indigent patients without cost to cash-strapped public budgets that will not pose such dangerous risks to the pharmaceutical supply of all Californians. Described below are reasons we seek your veto of this bill.

- Pharmacies in 2010 dispensed over 625 million prescriptions to patients in California. This is quite obviously a huge number of drugs, and California as the most populous state also has more medication dispensed to its residents each year than any other state. This board regulates the wholesalers, pharmacies, and the professional and ancillary staff within these facilities, that dispense, ship and store prescription medication and devices into, throughout and from California. In the US prescription medication is tightly regulated to preserve the integrity of the product, prevent unlicensed individuals from buying or selling drugs, and thus help ensure that the medication provided to patients is not counterfeit, misbranded, adulterated, outdated or otherwise nonsaleable. While the US and California have generally among the safest drug supplies in the world, in recent years there has been an increasing number of discoveries of adulterated and counterfeit drugs reaching patients in the US. Criminals have learned how lucrative selling counterfeit, adulterated and other nonsaleable

prescription drugs can be. Pharmacies, practitioners and wholesalers, looking for the best price in these hard economic times, will sometimes buy from entities they do not know in response to Internet or faxed ads offering medication at substantially low prices. These prescription drugs are often cheap because they may have been previously stolen, outdated, diluted, or previously dispensed and bought illegally from patients or care facilities to be resold into the drug supply. And once mixed into the legitimate pharmaceutical supply chain, it is impossible to visually detect potentially inefficacious drugs.

- In 2004, in response to Californians receiving counterfeit drugs from their pharmacies, California enacted the nation's most comprehensive requirements to establish a secure "chain of custody" in the distribution and sale of prescription drugs from manufacturer through wholesaler to pharmacy and practitioner. Based on a system envisioned by the FDA and twice legislatively postponed since 2004 (in 2006 and 2008), these requirements will take effect on a staggered basis from 2015 through July 2017. Called electronic pedigrees (or simply e-pedigree), each manufacturer's container that will be sold in California must have a unique number affixed at the time of manufacture that will be read and appended electronically at every sale as the container moves through the supply chain. This creates the chain of custody, whereby product insertions into the supply chain can be detected by downstream companies. Any medication sold in California after the effective date must have been manufactured, shipped and sold with the e-pedigree appended at each sale throughout the supply chain; a container cannot be retroactively appended with the information. As such, California with more than 10 percent of the US drug market has established a system that will likely be implemented nationally because at the time of manufacture, the manufacturer cannot segment that portion of medication that will be sold in California. This is a major undertaking for the board and certainly for the entire supply chain.
- With rare exception, dispensing of previously dispensed medication is not legal. The US drug distribution system provides that once a medication has been dispensed to a patient, it generally cannot be returned to the pharmacy for redistribution to another (unsuspecting) patient.[1] Instead, the medication must be destroyed. However, such medication still has value to entities that seek to acquire it to slip it back into the drug supply since these drugs can be obtained at low or no cost from patients, skilled nursing facilities, or resold to illegally acting wholesalers and others.

  Attachments to this letter provide pictures of California pharmacies that have been discovered accepting returned drugs from skilled nursing facilities and re-dispensing

[1] One exception is "bubble" or "blister" packaged medication which is frequently used in skilled nursing facilities. If such medication is redispensed, the original packaging must be retained and redispensed without the patient-specific information.

these medications in violation of law to patients. Also there are three articles discussing the large value of the drugs purchased back from patients that are then resold to others ($300 million in HIV meds in NY in April 2012, $500 million in HIV drugs by the FBI in NY in June, $55 million in prior sales from a wholesaler in the south).

Senate Bill 1329 as enrolled will establish an "underground" drug supply in California of previously dispensed medication that has been donated to county-owned or contracted pharmacies and free clinics by a number of locations. Some of this medication will reach the medically indigent, but based on the broadness of the new provisions, we believe some of this medication will be re-inserted into the main pharmaceutical supply chain to the detriment of all.

- Senate Bill 1329 will permit pharmacies that "principally" serve skilled nursing facilities, board and care homes or provide mail order deliveries, to accept unwanted medication back from skilled nursing facilities and other health facilities instead of having such waste destroyed by reverse distributers or waste haulers. This will allow the pharmacy to donate these drugs to the repositories and save the facilities the costs of appropriate removal and destruction. Regrettably, there is a great deal of wasted medication that originates from these care facilities; however, profit margins in pharmacies are such that few pharmacies will want to take on the task and expense of sorting and routing medication to repository facilities, and then absorbing the expense of destruction of the non-donated medication UNLESS they see a potential profit somewhere. Accepting such medication back after it has been dispensed makes it a free source of medication for these pharmacies, some of which will illegally re-insert the medication back into the supply chain. Even without SB 1329's broad provisions, the board has identified the redistribution of medication returned from skilled nursing patients being dispensed and charged to other patients as a problem with some pharmacies serving these facilities, and has disciplined facilities when this is discovered. However, SB 1329's authorization in law will undermine all efforts made to secure the supply chain by implementation of e-pedigree requirements. Previously dispensed medication should not be returned to a pharmacy but handled by reverse distributors and waste haulers that are licensed to handle and remove such non-saleable drugs. The board also notes some poor drafting of this section that will likely impede board enforcement actions. Specifically, Section 4 of the bill starts with "Notwithstanding any other law . . . " and then in subdivision (b) references ". . . in a manner consistent with state and federal law." -- seemingly both unlinking and directing compliance with existing law. This ambiguity and circular reasoning will make it hard for the board to discipline pharmacies that redistribute drugs returned from skilled nursing facilities.
- Senate Bill 1329 also will allow drug repositories themselves to transfer unwanted donated drugs they have received to other participating entities (county-owned or contracted pharmacies, free clinics), even outside the county. This will make it virtually

impossible to identify the origin of any drugs donated to a repository, or more importantly, attempt to identify and track the specific drugs and quantity where donated drugs actually were sent from. The result: mass movement of untracked medication that has been previously dispensed and may have been returned to a pharmacy for donation or to a repository facility, but transferred elsewhere.

- Senate Bill 1329 would broaden existing law for drug repositories to permit county owned or contracted pharmacies and free clinics to accept donations of previously dispensed medication from 10 new healthcare and community settings where patients reside. Of principal concern to the board is one of the proposed new donor sites -- large residential care homes where there are at least 16 residents. There are more than 7,800 of these facilities licensed in California, where residents in these facilities are encouraged to gain independent living skills. There is no requirement for licensed health care staff to be onsite in these facilities, but many residents are on various medications, and appropriate destruction of this medication when no longer needed is currently a problem (and an expensive problem). Residents are able to keep their own medication in their possession unless a physician orders centralized storage and handling. The board has concerns about how such medication that may have been in the possession of residents at one time or another, if donated, can be assured to be safe for use by a medically indigent patient. And even if centrally stored, there is no requirement about what facility staff or volunteers may have access to the medication. The board believes that donations from residential care facilities to the repository locations are likely to include all unwanted medication, whether in the appropriate packaging or previously centrally stored.

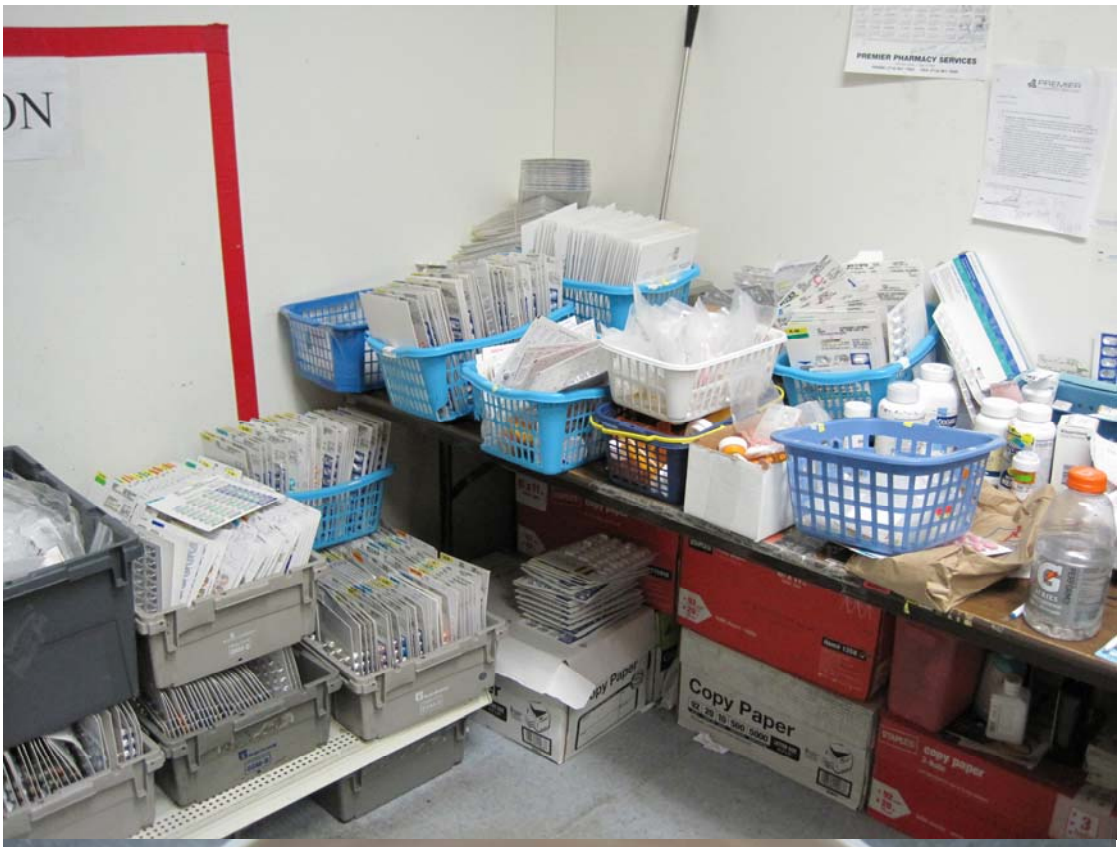
There are other ways to secure prescription drugs for medically indigent patients. For example, the Los Angeles County Department of Public Health has saved over $18 million in each of the last few years by using drug manufacturers' patient assistance programs to secure drugs for medically indigent patients. Such programs provide brand-name drugs to qualifying patients at no expense. These are not redistributed drugs, but new medications.

The expansion to California's drug repository law proposed in SB 1329 will undermine California's drug supply in ways that will be difficult to detect, prevent and prosecute. California currently has the strongest requirements in the US to guard against the introduction of counterfeit or adulterated drugs into the supply chain – enactment of SB 1329 will destroy the value of this effort. The board respectfully requests your veto of SB 1329.

Sincerely,

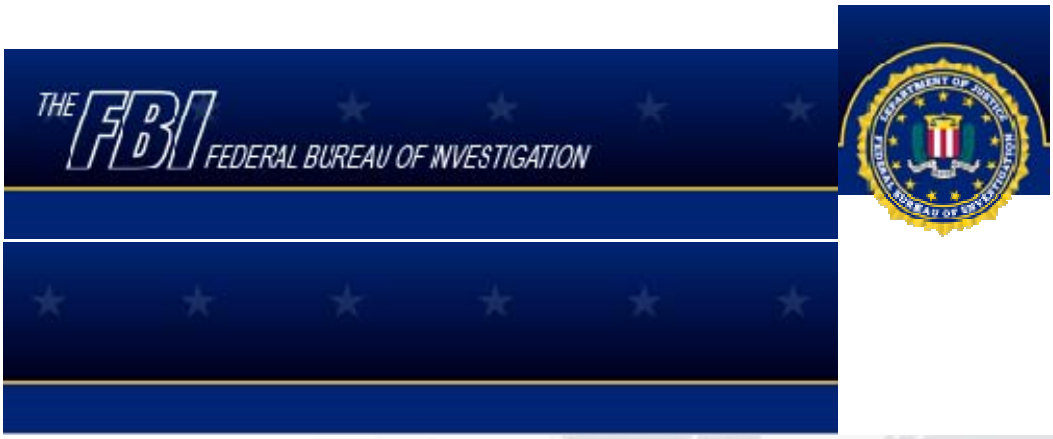
VIRGINIA HEROLD
Executive Officer

Attachment 1: Returned drugs from skilled nursing facilities to a California pharmacy under investigation.



Attachment 2:

$500 Million Prescription Diversion Identified in New York, June 2012



New York Field Office

Manhattan U.S. Attorney Announces Charges Against 48 Individuals in Massive Medicaid Fraud Scheme Involving the Diversion and Trafficking of Prescription Drugs
Scheme Caused Losses Estimated at More Than Half-a-Billion Dollars to Medicaid and is Believed to be the Largest Single Prescription Drug Diversion Scheme Ever Charged at One Time

U.S. Attorney's Office July 17, 2012

- Southern District of New York (212) 637-2600

Preet Bharara, the United States Attorney for the Southern District of New York; Janice K. Fedarcyk, the Assistant Director in Charge of the New York Field Office of the Federal Bureau of Investigation (FBI); Raymond W. Kelly, the Police Commissioner of the City of New York (NYPD); and Robert Doar, the Commissioner of the New York City Human Resources Administration (HRA), announced today the unsealing of charges against 48 defendants for their participation in a massive fraud scheme involving the unlawful diversion and trafficking of hundreds of millions of dollars' worth of prescription drugs that had previously been dispensed to Medicaid recipients in the New York City area ("second-hand" drugs), in a national underground market. As a result of the fraud, Medicaid lost more than an estimated $500 million in reimbursements for pills that were diverted into this second-hand black market. Forty-two of the defendants were charged in a superseding indictment, and six more were charged in a complaint.

Thirty-four of the defendants were arrested this morning in connection with today's charges. Fifteen defendants were taken into custody in New York and New Jersey, and an additional defendant from the area will surrender today. These 16 defendants will be presented and arraigned in Manhattan federal court before U.S. Magistrate Judge Frank Maas later this afternoon. Nineteen other defendants were arrested in Pennsylvania, Massachusetts, Florida, and Texas and are expected to appear today and tomorrow in federal courts in those states. The remaining defendants charged are at large.

Manhattan U.S. Attorney Preet Bharara said, "As alleged, these defendants ran a black market in prescription pills involving a double-dip fraud of gigantic proportions. It worked a fraud on Medicaid—in some cases, two times over—a fraud on pharmaceutical companies, a fraud on legitimate pharmacies, a fraud on patients who unwittingly bought second-hand drugs, and

ultimately, a fraud on the entire health care system. With the dozens of arrests we made today, we have taken a significant step toward exposing and shutting down the black market for second-hand drugs, and our investigation is very much ongoing."

FBI Assistant Director in Charge Janice K. Fedarcyk said, "The scheme to collect, aggregate, and resell costly prescription drugs was bad medicine in three ways: profiting so obscenely by breaking the law is the very definition of unjust enrichment. The scheme was theft, plain and simple, from a program funded by taxpayers. And the scheme posed serious health risks at both the collection and distribution ends. People with real ailments were induced to sell their medications on the cheap rather than take them as prescribed, while end-users of the diverted drugs were getting second-hand medicine that may have been mishandled, adulterated, improperly stored, repackaged, and expired."

NYPD Commissioner Raymond W. Kelly said, "It's one thing when people sell their blood for money; it's another when they sell their drugs, especially when the diversion compromises the pharmaceutical supply with tainted and outdated drugs."

HRA Commissioner Robert Doar said, "This case is an egregious example of individuals preying on our most vulnerable population. The diversion, repackaging, and reselling of HIV/AIDS medications, in some cases expired, is a danger to our public health. The integrity of the Medicaid Program has been threatened by these criminals who have used taxpayer dollars for the opposite reasons for which they are intended. But make no mistake, together with our law enforcement partners, we will continue to pursue these types of criminals and prosecute them to the fullest extent of the law."

The following allegations are based on the superseding indictment, the complaint, and other documents unsealed today in Manhattan federal court:

The prescription drugs involved in this scheme were drugs designed to treat various illnesses, including HIV, schizophrenia, and asthma, and were non-controlled substances that did not lend themselves to abuse. These second-hand drugs were originally dispensed to Medicaid recipients in the New York City area who then sold them into collection and distribution channels that ultimately ended at pharmacies for resale to unsuspecting consumers. The defendants and their co-conspirators profited by exploiting the difference between the cost to the patient of obtaining the prescription drugs through Medicaid, which was usually nothing, and the hundreds of dollars per bottle that pharmacies paid to purchase those drugs to sell to their customers. In order to maximize their profits, the defendants and their co-conspirators targeted the most expensive drugs, which often cost more than $1,000 per bottle.

The Fraudulent Distribution and Trafficking Scheme

The lowest level participants in the scheme (the "Medicaid beneficiaries") were typically AIDS patients or individuals who suffered from other illnesses that required expensive drug therapies. Using their Medicaid benefits to cover the costs, the Medicaid beneficiaries filled prescriptions for month-long supplies of drugs at pharmacies throughout the New York City area and then sold them to "collectors" for cash instead of using them for treatment. These transactions occurred at street corners and bodegas in and around New York City, including in the Washington Heights neighborhood of Manhattan and in the Bronx. Collectors then sold the

second-hand bottles to higher level participants in the scheme ("aggregators"), who typically bought large quantities of second-hand drugs from multiple collectors. These transactions repeated themselves at increasingly higher levels of aggregators who purchased the drugs from multiple, lower level aggregators. The pills were ultimately sold to wholesale prescription drug distribution companies ("corrupt distribution companies"), which then sold them to pharmacies and to other wholesale prescription distribution drug companies across the United States. Ultimately, these pharmacies then dispensed the second-hand drugs to unsuspecting customers, some of whom likely were Medicaid beneficiaries. Therefore, in some cases, Medicaid would have reimbursed patients for the same drugs twice—the second time for drugs that were misbranded, adulterated, and possibly expired—and would thereby have been defrauded twice.

The defendants charged in the superseding indictment and the complaint include collectors, aggregators, and owners and operators of the corrupt distribution companies who were carrying out this scheme in states including New York, New Jersey, Pennsylvania, Florida, Texas, Massachusetts, Utah, Nevada, Louisiana, and Alabama.

In addition, several defendants were also charged with narcotics trafficking offenses for buying and reselling drugs including Oxycodone and Oxymorphone.

The Fraudulent Labeling Scheme

Because the prescription drugs involved in the scheme were not drugs of abuse and were ultimately going to be resold in the legal drug distribution chain, it was essential that they be packaged in bottles that appeared to contain new drugs that came directly from the manufacturer via authorized and licensed wholesale distributors. Therefore, the defendants and their co-conspirators had to restore the previously dispensed bottles to their original appearance, with the manufacturer's label still intact but without the patient labels that pharmacies affix when dispensing drugs to a patient. After purchasing the second-hand bottles originally dispensed to Medicaid beneficiaries, the defendants and their co-conspirators used lighter fluid and other means to dissolve the adhesive on the patient labels so that they could be removed. During the process, the manufacturers' labels sometimes became damaged, and/or the second-hand drugs were close to their expiration dates or had already expired. When the bottles were not resaleable because of damaged manufacturers' labels or expiration date problems, some of the defendants replaced the original manufacturers' labels with counterfeit labels and/or altered the labels to backdate their expiration dates. Some of these counterfeit prescription drug manufacturers' labels were obtained by two of the defendants from the Dominican Republic. In other instances, the defendants and their co-conspirators removed the drugs from the bottles and trafficked in loose pills, which were then completely untraceable.

E-mails obtained by search warrant revealed that a certain subset of the defendants bought and sold more than $62 million worth of second-hand prescription drugs during an approximately 12-month time period during the conspiracy, which they meticulously documented in a business-like manner through purchase orders and receipts scanned onto their computers and uploaded into e-mail accounts.

The Second-Hand Pills

The second-hand pills that found their way back into the legal drug distribution stream were

potentially dangerous to the unwitting consumers who purchased them for several reasons. For example, the defendants and their co-conspirators stored the drugs in uncontrolled conditions, such as car trunks, residences, and rented storage facilities, which would have compromised the medical efficacy of the drugs over time.

During the investigation, the FBI seized more than $16 million worth of second-hand prescription drugs, comprised of more than 33,000 bottles and more than 250,000 loose pills, kept in uncontrolled and sometimes egregious conditions by various defendants and their co-conspirators.

* * *

Charts identifying each defendant, the charges, and the maximum penalties are below. The indicted case is assigned to U.S. District Judge Denise L. Cote.

Mr. Bharara praised the efforts of the FBI's Health Care Fraud Task Force and thanked FBI, NYPD, and HRA for their work on the case. The New York FBI Health Care Fraud Task Force was formed in 2007 in an effort to combat health care fraud in the greater New York City area. The task force is comprised of agents, officers, and investigators from the FBI, NYPD, the New York State Insurance Fraud Bureau, U.S. Department of Labor, U.S. Office of Personnel Management Inspector General, U.S. Food and Drug Administration, New York State Attorney General's Office, New York State Office of Medicaid Inspector General, New York State Health and Hospitals Inspector General, and the National Insurance Crime Bureau.

Mr. Bharara thanked the Drug Enforcement Administration, Immigration and Customs Enforcement's Homeland Security Investigations, and the New York State Office of the Medicaid Inspector General for their assistance. He also thanked the FBI's Boston, Houston, Miami, Newark, Philadelphia, and Salt Lake City Field Offices, as well as the U.S. Attorney's offices in New Jersey, Massachusetts, Texas (Southern), Florida (Southern), Pennsylvania (Eastern), and Utah for their assistance in the investigation.

If you think you may have purchased second-hand prescription drugs or were otherwise victimized by this scheme, you can call the FBI Hotline at 212-384-3555.

The case is being prosecuted by the Office's Organized Crime Unit. Assistant U.S. Attorneys Jason A. Masimore and Russell Capone are in charge of the prosecution. Assistant U.S. Attorney Alexander Wilson of the Office's Asset Forfeiture Unit is responsible for the forfeiture of assets.

The charges contained in the indictment and the complaint are merely accusations, and the defendants are presumed innocent unless and until proven guilty.

* * *

U.S. v. Viera, et al.

Count	Charge	Defendants	Maximum Penalties
1	Conspiracy to commit wire fraud, mail fraud, and healthcare fraud	Juan Carlos Viera Jose Manuel Dominguez Julio Dominguez Carlos Alberto Padron Juan Manuel Tavarez Padilla Juan Tavarez Aura Catalina Tavarez Edwin M. Tavarez Israel Tacher Roberto Tacher Vanessa Rosario Eligio Armas Eduardo Diaz Carlos Peralta Joselito Peralta Juan Carlos Peralta Hanser Olivo Liranzo Kelvin Manuel Martinez Taveras Glenn Luis Cabrera Fary R. Caba Padilla Miguel Padilla Americo Luis Garcia Dominguez Wilfred Rodriguez Jose Ramon Gonzalez Alex Justo Yoel Fernandez Rivero Amauris A. Rosario Jacqueline Jimenez Luis Santana Bayohan Diaz Paulino Cayetano Armando Garcia Sergio Novo Lazaro Ospina	0 years in prison
2	Conspiracy to commit adulteration and misbranding offenses and the unlawful wholesale distribution of prescription drugs	Juan Carlos Viera Jose Manuel Dominguez Julio Dominguez Carlos Alberto Padron Juan Manuel Tavarez Padilla Juan Tavarez Aura Catalina Tavarez Edwin M. Tavarez Israel Tacher Roberto Tacher Vanessa Rosario Eligio Armas Eduardo Diaz	Five years in prison

		Carlos Pera Joselito Peralta Juan Carlos Peralta Hanser Olivo Liranzo Kelvin Manuel Martinez Taveras Glenn Luis Cabrera Fary R. Caba Padilla Miguel Padilla Americo Luis Garcia Dominguez Wilfred Rodriguez Jose Ramon Gonzalez Alex Justo Yoel Fernandez Rivero Amauris A. Rosario Jacqueline Jimenez Luis Santana Bayohan Diaz Paulino Cayetano Armando Garcia Sergio Novo Lazaro Ospina	
3	Conspiracy to commit trafficking in counterfeit goods	Vanessa Rosario Joselito Peralta	10 years in prison
4	Narcotics conspiracy	Juan Manuel Tavarez Padilla Juan Tavarez Aura Catalina Tavarez Vanessa Rosario Joselito Peralta Hanser Olivo Liranzo Amauris A. Rosario Brenda Santos Ira Karp Joel Gabriel Casado	20 years in prison
5	Narcotics conspiracy	Luis Santana Bayohan Diaz Luis Abreu Paulino Cayetano Jose Felipe Benito Duran Arelis Lee Milagros Acevedo	20 years in prison

U.S. v. Oria, et al.

Count	Charge	Defendants	Maximum Penalties
1	Conspiracy to commit mail fraud and healthcare fraud	Alex Oria Joe H. Nelson Kenneth Nelson Conrado Vazquez Efren Ruiz Abel Gonzalez	20 years in prison
2	Conspiracy to commit money laundering	Alex Oria Joe H. Nelson Kenneth Nelson	20 years in prison

Defendants' Ages and Residencies

Defendant	Residence	Age
Juan Carlos Vier	Hialeah, Florida	49
Jose Manuel Dominguez	Miami, Florida	62
Julio Dominguez	Miami, Florida	60
Carlos Alberto Padron	Miami, Florida	54
Juan Manuel Tavarez Padilla	Cliffside Park, New Jersey	30
Juan Tavarez	New York, New York	58
Aura Catalina Tavarez	New York, New York	36
Edwin M. Tavarez	Cliffside Park, New Jersey	26
Israel Tacher	Miami, Florida	62
Robert Tacher	Miami, Florida	37
Vanessa Rosario	Cutler Bay, Florida	28
Eligio Armas	North Bergen, New Jersey	54
Eduardo Diaz	Cliffside Park, New Jersey	58
Carlos Peralta	West New York, New Jersey	49
Joselito Peralta	Ridgefield Park, New Jersey	37
Juan Carlos Peralta	Ridgefield Park, New Jersey	24
Hanser Olivo LIRANZO	Fairview, New Jersey	32
Kelvin Manuel Martinez Taveras	Bronx, New York	33
Glenn Luis Cabrera	Ridgefield Park, New Jersey	22
Fary R. Caba Padilla	Bronx, New York	21

Miguel Padilla	Bronx, New York	62
Americo Luis Garcia Dominguez	Miami, Florida	29
Wilfred Rodriguez	Brooklyn, New York	49
Jose Ramon Gonzalez	New York, New York	48
Alex Justo	New York, New York	37
Yoel Fernandez Rivero	Miami, Florida	32
Amauris A. Rosario	Bronx, New York	31
Jacqueline Jimenez	New York, New York	37
Luis Santana	Richmond Hill, New York	39
Bayohan Diaz	Richmond Hill, New York	27
Paulino Cayetano	Bronx, New York	36
Armando Garcia	Guttenberg, New Jersey	40
Sergio Novo	North Arlington, New Jersey	74
Lazaro Ospina	Bloomfield, New Jersey	71
Brenda Santos	Philadelphia, Pennsylvania	34
Ira Karp	New York, New York	77
Luis Abreu	Worcester, Massachusetts	32
Joel Gabril Casado Gabriel	Bronx, New York	27
Jose Felipe	Brooklyn, New York	47
Benito Duran	Philadelphia, Pennsylvania	38
Arelis Lee	Brooklyn, New York	56
Milagros Acevedo	Brooklyn, New York	48
Alex Oria	Missouri City, Texas	55
Joseph Nelson	Sugar Land, Texas	75
Kenneth Nelson	Sugar Land, Texas	52
Conrado Vazquez	Miami, Florida	40
Efren Ruiz	Hialeah, Florida	42
Abel Gonzalez	Miami, Florida	36

Attachment 3: $274 Million in Diverted HIV Drugs Discovered in NY, April 2012

A.G. Schneiderman Announces Arrests In $274 Million Black Market Prescription Drug Operation

Investigation Leads To Arrests & Charges Of Four Ringleaders Distributing Black Market HIV Medication Through Suffolk and Brooklyn Pharmacies

A.G., OMIG Collaborate To Shut Down Massive Money Laundering & Bribery Scheme That Cost The NYS Medicaid Program $155 Million

Schneiderman: We Will Protect Vulnerable New Yorkers And Taxpayer Dollars At All Costs

NEW YORK- Attorney General Eric T. Schneiderman today announced the arrests and indictment of four ringleaders of a massive scheme to distribute black market prescription HIV drugs and defraud the Medicaid Program of $155 million. After an investigation code-named "Operation Black Market Meds," the Attorney General's Medicaid Fraud Control Unit shut down an illegal operation that was distributing HIV prescription drugs obtained on the black market through MOMS pharmacy, a high-volume pharmacy with satellites in Suffolk County and Brooklyn. MOMS, and its parent company Allion Healthcare, then dispensed the illegally obtained drugs to Medicaid recipients, and billed the New York State Medicaid program for these un-sellable drugs.

The scheme endangered patients by exposing them to drugs of unknown origin and potency, and in some cases, drugs that were mislabeled or potentially expired. In addition to today's criminal charges, the Attorney General is seeking $155 million in civil penalties from the defendants.

"The ringleaders of this complex scheme not only cheated the state Medicaid program out of millions of dollars, but preyed on some of New York's most vulnerable patients just to make a quick buck. These crimes are intolerable, and the perpetrators will be held accountable for breaking the law," said **Attorney General Schneiderman**. "Our office will continue to protect taxpayers and consumers from schemes that threaten the safety of the public."

The indictment, which was unsealed today in New York State Supreme Court in Suffolk County by Judge James C. Hudson, charges four defendants with Class B felonies including Grand Larceny in the First Degree for thefts from the Medicaid Program and the parent company of the pharmacies, Criminal Diversion of Prescription Medications and Prescriptions in the First Degree (a Class C felony), Money Laundering in the First Degree and Second Degree (a Class C felony); Class E felony crimes of Commercial Bribery and Commercial Bribe Receiving in the First Degree, Offering a False Instrument for Filing in the First Degree, and Conspiracy in the Fourth Degree, among other charges. Each of the class B felony charges carries a maximum of 8 1/3 to 25 years imprisonment.

According to the indictment and forfeiture complaint, beginning in September 2008, Glenn Schabel, the supervising pharmacist and compliance officer for MOMS pharmacy, accepted bribes to purchase in excess of $274 million worth of black market HIV medications from a web of shell companies. The prescription drugs were obtained by various illegal means and the batches may have included unused pills that had previously been dispensed to individuals, medications stolen from manufacturers, or drugs that had expired. The shell companies were controlled by Stephen Manuel Costa, a 27-year-old Florida resident who incorporated four separate entities as "wholesale" distributors in order to disguise the sale of the diverted medications. Costa furnished millions of the black market HIV medications, and dispensed the prescriptions to MOMS patients, many of whom were Medicaid recipients. Allion, under the direction of Schabel, continued to bill Medicaid, knowing the drugs were purchased illegally.

Attorney General Schneiderman's investigation also revealed that Ira Gross, another licensed pharmacist, brokered the sale of the illegally diverted drugs between Schabel and Costa. The fourth defendant, Harry Abolafia, created false invoices for Costa's companies—SMC Distributors, Fidelity Wholesale, Optimus Wholesale, and Nuline Pharmaceuticals—in order to make the transactions appear to be legitimate. In total, on behalf of Allion, Schabel purchased $274 million worth of black market HIV medications from Costa. For their efforts, Schabel, Gross and Abolafia were all paid a portion of Costa's profit: $5,336,465, $21,165,374 and $1,429,612, respectively.

In these types of black market operations, drugs are obtained from a variety of sources, and can be rebottled with fake labels and serial numbers, broken seals, or contain different medications than what's indicated on the labels. As a result, patients are exposed to potential adverse drug interactions, overdoses, or a decline in their condition by not getting the treatment they were prescribed.

The indictment charges that at least $155 million in false claims were made to the New York State Medicaid Program after the drugs were dispensed.

Through the use of telephone wiretaps, the Attorney General's Medicaid Fraud Control Unit intercepted a delivery of over $1 million worth of prescription HIV medications from one of Costa's companies, Nuline Pharmaceuticals, to the Melville distribution center of MOMS pharmacy. The investigators simultaneously executed a search warrant, and, with the assistance of a team of pharmacists from the New York State Office of the Medicaid Inspector General (OMIG), seized millions of dollars of diverted HIV medications.

Earlier this year, the Attorney General also seized millions of dollars in assets of the defendants through a forfeiture complaint filed in conjunction with the execution of a search warrant at MOMS pharmacy in Melville.

"Creating a black market with taxpayer-funded HIV medication is an insidious and costly fraud," said **Medicaid Inspector General James C. Cox**. "Our pharmacy investigators were there as part of the search warrant team and offered important testimony to the grand jury to obtain an indictment that was

unsealed today. I am proud of the work that not only these investigators did, but also the work of our entire staff in cases such as these."

The Attorney General thanked the New York State Office of the Medicaid Inspector General, under the direction of Medicaid Inspector General James Cox, and the field staff of OMIG pharmacists and other specialists. The New York City Office of Special Narcotics Prosecutor and the US Drug Enforcement Administration, the US Food and Drug Administration and the Department of Health and Human Services, Office of Inspector General provided valuable information and assistance during the investigation.

The indictment is being prosecuted by Medicaid Fraud Control Unit Special Assistant Attorneys General Vernitta Chambers and Adam Shlahet and MFCU Deputy Regional Director Thomas O'Hanlon; the forfeiture action was filed by Special Assistant Attorneys General Diana Elkind and Andrew Gropper. The investigation was conducted by MFCU Senior Investigators Victor Maldonado and Lawrence Riccio and a squad of MFCU investigators led by Supervising Investigator Thomas Creelman. The Medicaid Fraud Control Unit is directed by Special Deputy Attorney General Monica Hickey-Martin.

The charges against the defendants are merely accusations and the defendants are presumed innocent until and unless proven guilty in a court of law.

Attachment 4: More than $55 million paid for Gray Market Drugs; August 2012

Altec Medical Pleads Guilty To Using Gray-Market Supplier.

Modern Healthcare (8/11, Carlson, Subscription Publication) reported, "Altec Medical, Easley, S.C., will pay a fine of $2 million and forfeit another $1 million after the corporation pleaded guilty to buying pharmaceuticals from a gray-market supplier and then reintroducing them into the US drug market for sale at retail pharmacies." In addition, the company "was sentenced to a year of probation by US District Judge Robert Scola in Miami after pleading guilty to conspiring to defraud the US Food and Drug Administration." The firm was accused of conspiring with William Rodriguez who pleaded guilty in June 2012 to charges of "conspiracy and money laundering" with prosecutors saying that Altec paid him "about $55 million between 2007 and 2009 for prescription drugs that company officials knew had been illegally diverted" and "then created fake 'drug pedigrees' that purported to show that the unidentified drugs had been acquired legally

Senate Bill No. 1481

CHAPTER 874

An act to amend Sections 1206.5, 1211, 1265, and 4052.4 of, and to add Section 1206.6 to, the Business and Professions Code, relating to clinical laboratories.

[Approved by Governor September 30, 2012. Filed with Secretary of State September 30, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1481, Negrete McLeod. Clinical laboratories: community pharmacies.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to perform skin puncture in the course of performing clinical laboratory tests classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA). Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health, subject to certain exceptions. Existing law prohibits a person from performing a clinical laboratory test classified as waived unless the test is performed under the overall operation and administration of the laboratory director who meets specified requirements and the test is performed by certain persons, as specified.

This bill would eliminate that laboratory director requirement with respect to certain tests classified as waived under CLIA that are approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit and are performed by a pharmacist at a community pharmacy upon customer request, provided that the pharmacy obtains a CLIA certificate of waiver and a registration from the State Department of Public Health and complies with all other requirements governing clinical laboratories, as specified. The bill would make other related conforming changes.

This bill would incorporate additional changes to Section 1206.5 of the Business and Professions Code made by AB 761 that would become operative only if both this bill and AB 761 are enacted and this bill is chaptered after AB 761.

The people of the State of California do enact as follows:

SECTION 1. Section 1206.5 of the Business and Professions Code is amended to read:

1206.5. (a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Sections 1206.6 and 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist, a licensed dentist, or a licensed naturopathic doctor, if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A person licensed under Chapter 6.5 (commencing with Section 2840).

(8) A perfusionist if authorized by and performed in compliance with Section 2590.

(9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.

(11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1.

(12) A naturopathic assistant, as defined in Sections 3613 and 3640.2, if the waived test is performed pursuant to a specific authorization meeting the requirements of Sections 3613 and 3640.2.

(13) Other health care personnel providing direct patient care.

(14) Any other person performing nondiagnostic testing pursuant to Section 1244.

(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the

qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A perfusionist if authorized by and performed in compliance with Section 2590.

(8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(10) Any person if performing blood gas analysis in compliance with Section 1245.

(11) (A) A person certified or licensed as an "Emergency Medical Technician II" or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.

(B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a "preceptor program" means

an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.

(12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient's physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.

(c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person's licensure.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person's certification.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A perfusionist if authorized by and performed in compliance with Section 2590.

(7) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(8) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(9) Any person if performing blood gas analysis in compliance with Section 1245.

(10) Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient's physician and surgeon

or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:

(1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.

(3) A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

SEC. 1.5. Section 1206.5 of the Business and Professions Code is amended to read:

1206.5. (a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Sections 1206.6 and 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist, a licensed dentist, or a licensed naturopathic doctor, if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A person licensed under Chapter 6.5 (commencing with Section 2840).

(8) A perfusionist if authorized by and performed in compliance with Section 2590.

(9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.

(11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1.

(12) A naturopathic assistant, as defined in Sections 3613 and 3640.2, if the waived test is performed pursuant to a specific authorization meeting the requirements of Sections 3613 and 3640.2.

(13) A licensed optometrist as authorized under Chapter 7 (commencing with Section 3000).

(14) Other health care personnel providing direct patient care.

(15) Any other person performing nondiagnostic testing pursuant to Section 1244.

(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A perfusionist if authorized by and performed in compliance with Section 2590.

(8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(10) Any person if performing blood gas analysis in compliance with Section 1245.

(11) (A) A person certified or licensed as an "Emergency Medical Technician II" or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.

(B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a "preceptor program" means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.

(12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient's physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.

(c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the

qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person's licensure.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person's certification.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A perfusionist if authorized by and performed in compliance with Section 2590.

(7) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(8) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(9) Any person if performing blood gas analysis in compliance with Section 1245.

(10) Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:

(1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.

(3) A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

SEC. 2. Section 1206.6 is added to the Business and Professions Code, to read:

1206.6. Subdivision (a) of Section 1206.5 shall not apply to a pharmacist at a community pharmacy who, upon customer request, performs only blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived under CLIA and are approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, provided that all of the following requirements are satisfied:

(a) The pharmacy obtains a valid CLIA certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations. For purposes of CLIA, the person identified as responsible for directing and supervising testing oversight and decisionmaking shall be the pharmacist-in-charge, as defined in Section 4036.5.

(b) The pharmacy obtains a registration from the department pursuant to Section 1265 and complies with this chapter.

(c) The tests are performed only by a pharmacist, as defined in Section 4036, in the course of performing routine patient assessment procedures in compliance with Section 4052.4.

SEC. 3. Section 1211 of the Business and Professions Code is amended to read:

1211. (a) As used in this chapter, "owner" means any person with an ownership or control interest in a clinical laboratory.

(b) "Person with an ownership or control interest" means a person, partnership, or corporation that meets any of the following descriptions:

(1) Has an ownership interest totaling 5 percent or more in a clinical laboratory.

(2) Has an indirect ownership interest equal to 5 percent or more in a clinical laboratory.

(3) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a clinical laboratory.

(4) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the clinical laboratory if that interest equals at least 5 percent of the value of the property or assets of the clinical laboratory.

(5) Is an officer or director of a clinical laboratory that is organized as a corporation.

(6) Is a partner in a clinical laboratory that is organized as a partnership with no more than 25 partners, general or limited.

(7) Is a partner who exercises any operational or managerial control over a clinical laboratory organized as a partnership with more than 25 partners, general or limited.

(c) As used in this chapter "ownership interest" means the possession of equity in capital, stock, or profits.

(d) "Indirect ownership interest" means an ownership interest in an entity that has an ownership interest in a clinical laboratory, and includes an ownership interest in any entity that has an indirect ownership interest in a clinical laboratory.

(e) "Change in ownership" means any change in the persons who are owners.

(f) "Major change in ownership" means a change in ownership where 50 percent or more of the ownership interest is owned by persons other than the owners to whom the current clinical laboratory license or registration is issued.

(g) "Change in name" means any change in the name under which the laboratory operates or is doing business.

(h) "Change in location" means any change in the street and city address, or the site or place within the street and city address, for which a license or registration is issued.

(i) "Change in laboratory director" means any change in the laboratory director or directors to whom the current license or registration is issued.

(j) "Major change in laboratory directorship" means a change in laboratory director or directors resulting in the situation where less than 50 percent of the laboratory directors to whom the current laboratory license or registration is issued remain after the change.

(k) For purposes of this section, in the case of a pharmacy that applies for a registration pursuant to Section 1206.6, "laboratory director" means the pharmacist-in-charge identified pursuant to subdivision (a) of Section 1206.6.

SEC. 4. Section 1265 of the Business and Professions Code is amended to read:

1265. (a) (1) A clinical laboratory performing clinical laboratory tests or examinations classified as of moderate or of high complexity under CLIA shall obtain a clinical laboratory license pursuant to this chapter. The department shall issue a clinical laboratory license to any person who has applied for the license on forms provided by the department and who is found to be in compliance with this chapter and the regulations pertaining thereto. No clinical laboratory license shall be issued by the department unless the clinical laboratory and its personnel meet the CLIA requirements for laboratories performing tests or examinations classified as of moderate or high complexity, or both.

(2) A clinical laboratory performing clinical laboratory tests or examinations subject to a certificate of waiver or a certificate of provider-performed microscopy under CLIA, shall register with the department. The department shall issue a clinical laboratory registration to any person who has applied for the registration on forms provided by the department and is found to be in compliance with this chapter, the regulations pertaining thereto, and the CLIA requirements for either a certificate of waiver or a certificate of provider-performed microscopy.

(b) An application for a clinical laboratory license or registration shall include the name or names of the owner or the owners, the name or names

of the laboratory director or directors, the name and location of the laboratory, a list of the clinical laboratory tests or examinations performed by the laboratory by name and total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance, or proficiency testing purposes). The application shall also include a list of the tests and the test kits, methodologies, and laboratory equipment used, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures, and any other relevant information as may be required by the department. If the laboratory is performing tests subject to a provider-performed microscopy certificate, the name of the provider or providers performing those tests shall be included on the application. Application shall be made by the owners of the laboratory and the laboratory directors prior to its opening. A license or registration to conduct a clinical laboratory if the owners are not the laboratory directors shall be issued jointly to the owners and the laboratory directors and the license or registration shall include any information as may be required by the department. The owners and laboratory directors shall be severally and jointly responsible to the department for the maintenance and conduct thereof or for any violations of this chapter and regulations pertaining thereto.

(c) The department shall not issue a license or registration until it is satisfied that the clinical laboratory will be operated within the spirit and intent of this chapter, that the owners and laboratory directors are each of good moral character, and that the granting of the license will not be in conflict with the interests of public health.

(d) A separate license or registration shall be obtained for each laboratory location, with the following exceptions:

(1) Laboratories that are not at a fixed location, that is, laboratories that move from one testing site to another, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, may apply for and obtain one license or registration for the designated primary site or home base, using the address of that primary site.

(2) Not-for-profit, or federal, state, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests, as defined under CLIA, per license) public health testing may apply for and obtain a single license or registration.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction, may file a single application or multiple applications for a license or registration of laboratory locations within the same campus or street address.

(4) Locations within a single street and city address that are under common ownership may apply for and obtain a single license or registration or multiple licenses or registrations, at the discretion of the owner or owners.

(e) (1) A license or registration shall be valid for one year unless revoked or suspended. A clinical laboratory license or registration shall be automatically revoked 30 days from a major change of laboratory

directorship or ownership. The clinical laboratory shall be required to submit a completed application for a new clinical laboratory license or registration within those 30 days or cease engaging in clinical laboratory practice.

(2) If a clinical laboratory intends to continue to engage in clinical laboratory practice during the 30 days after a major change in directorship occurs and before the laboratory license or registration is automatically revoked, the laboratory owner may appoint an interim director who meets the requirements of this chapter and CLIA. The interim director shall be appointed within five business days of the major change of the directorship. Written notice shall be provided to the department of the appointment of the laboratory director pursuant to this paragraph within five business days of the appointment.

(f) If the department does not within 60 days after the date of receipt of the application issue a license or registration, it shall state the grounds and reasons for its refusal in writing, serving a copy upon the applicant by certified mail addressed to the applicant at his or her last known address.

(g) The department shall be notified in writing by the laboratory owners or delegated representatives of the owners and the laboratory directors of any change in ownership, directorship, name, or location, including the addition or deletion of laboratory owners or laboratory directors within 30 days. However, notice of change in ownership shall be the responsibility of both the current and new owners. Laboratory owners and directors to whom the current license or registration is issued shall remain jointly and severally responsible to the department for the operation, maintenance, and conduct of the clinical laboratory and for any violations of this chapter or the regulations adopted thereunder, including any failure to provide the notifications required by this subdivision, until proper notice is received by the department. In addition, failure of the laboratory owners and directors to notify the department within 30 days of any change in laboratory directors, including any additions or deletions, shall result in the automatic revocation of the clinical laboratory's license or registration.

(h) The withdrawal of an application for a license or registration or for a renewal of a license, or registration, issuable under this chapter, shall not, after the application has been filed with the department, deprive the department of its authority to institute or continue a proceeding against the applicant for denial of the license, registration, or renewal upon any ground provided by law or to enter an order denying the license, registration, or renewal upon any such ground, unless the department consents in writing to the withdrawal.

(i) The suspension, expiration, or forfeiture by operation of law of a license or registration issued under this chapter, or its suspension, forfeiture, or cancellation by order of the department or by order of a court of law, or its surrender without the written consent of the department, shall not deprive the department of its authority to institute or continue an action against a license or registration issued under this chapter or against the laboratory owner or laboratory director upon any ground provided by law or to enter

an order suspending or revoking the license or registration issued under this chapter.

(j) (1) Whenever a clinical laboratory ceases operations, the laboratory owners, or delegated representatives of the owners, and the laboratory directors shall notify the department of this fact, in writing, within 30 calendar days from the date a clinical laboratory ceases operation. For purposes of this subdivision, a laboratory ceases operations when it suspends the performance of all clinical laboratory tests or examinations for 30 calendar days at the location for which the clinical laboratory is licensed or registered.

(2) (A) Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.

(B) For purposes of this subdivision, "medical records" means the test requisition or test authorization, or the patient's chart or medical record, if used as the test requisition, the final and preliminary test or examination result, and the name of the person contacted if the laboratory test or examination result indicated an imminent life-threatening result or was of panic value.

(C) For purposes of this subdivision, "laboratory records" means records showing compliance with CLIA and this chapter during a laboratory's operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.

(D) Information contained in medical records and laboratory records shall be confidential, and shall be disclosed only to authorized persons in accordance with federal, state, and local laws.

(3) The department or any person injured as a result of a laboratory's abandonment or failure to retain records pursuant to this section may bring an action in a court of proper jurisdiction for any reasonable amount of damages suffered as a result thereof.

(k) For purposes of this section, in the case of a pharmacy that applies for a registration pursuant to Section 1206.6, "laboratory director" means the pharmacist-in-charge identified pursuant to subdivision (a) of Section 1206.6.

SEC. 5. Section 4052.4 of the Business and Professions Code is amended to read:

4052.4. Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this section,

"routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

SEC. 6. Section 1.5 of this bill incorporates amendments to Section 1206.5 of the Business and Professions Code proposed by both this bill and Assembly Bill 761. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2013, (2) each bill amends Section 1206.5 of the Business and Professions Code, and (3) this bill is enacted after Assembly Bill 761, in which case Section 1 of this bill shall not become operative.

O

BILL NUMBER: SB 419
VETOEDDATE: 09/28/2012

To the Members of the California State Senate:

I am returning Senate Bill 419 without my signature.

This bill requires a pharmaceutical manufacturer to submit an already required report electronically to the Department of Resources Recycling and Recovery, and then to post the report on its own Web site.

This is a matter we can handle administratively.

Sincerely,

Edmund G. Brown Jr.

Senate Bill No. 419

Passed the Senate April 25, 2011

_____

Secretary of the Senate

Passed the Assembly August 30, 2012

_____

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day of _____, 2012, at _____ o'clock ___M.

_____

Private Secretary of the Governor

Corrected 9-7-12

CHAPTER _____

An act to amend Sections 47115 and 47116 of the Public Resources Code, relating to solid waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 419, Simitian. Solid waste: home-generated sharps.

Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices. The manufacturer is required to post and maintain a copy of the plan on its Internet Web site.

This bill would require the above plan to be submitted in an electronic format as prescribed by the department. The bill would require the manufacturer to post and maintain a copy of the plan in a readily accessible location on its Internet Web site.

The people of the State of California do enact as follows:

SECTION 1. Section 47115 of the Public Resources Code is amended to read:

47115. A pharmaceutical manufacturer that sells or distributes a medication in California that is usually intended to be self-injected at home through the use of a hypodermic needle, pen needle, intravenous needle, or any other similar device, shall, on or before July 1, 2010, and annually thereafter, submit to the department, a plan that describes how the manufacturer supports the safe collection and proper disposal of the waste devices. The plan shall be submitted in an electronic format as prescribed by the department.

SEC. 2. Section 47116 of the Public Resources Code is amended to read:

47116. (a) The manufacturer shall post and maintain a copy of the plans required pursuant to Section 47115 in a readily accessible location on its Internet Web site.

(b) The department shall post and maintain copies of the plans submitted by the manufacturers pursuant to Section 47115 on its Internet Web site.

Approved _____, 2012

_____

Governor

AMENDED IN ASSEMBLY AUGUST 27, 2012

AMENDED IN ASSEMBLY AUGUST 24, 2012

AMENDED IN ASSEMBLY JUNE 27, 2012

AMENDED IN ASSEMBLY JUNE 26, 2012

AMENDED IN SENATE JANUARY 4, 2012

AMENDED IN SENATE APRIL 26, 2011

AMENDED IN SENATE MARCH 22, 2011

SENATE BILL No. 616

Introduced by Senator DeSaulnier

February 18, 2011

An act to add Section 805.8 to the Business and Professions Code, and to amend Section 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 616, as amended, DeSaulnier. Controlled substances: reporting.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

Existing law requires dispensing pharmacies and clinics to report, on a weekly basis, specified information for each prescription of Schedule

II, Schedule III, or Schedule IV controlled substances, to the department, as specified.

This bill would establish the CURES Fund within the State Treasury to receive funds to be allocated, *upon appropriation by the Legislature,* to the Department of Justice for the purposes of funding CURES, and would make related findings and declarations.

This bill would, if insufficient funds exist to cover operational costs of CURES or a permanent and ongoing funding source is not identified for CURES, require the Medical Board of California, the Dental Board of California, the *California* State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine to increase the licensure, certification, and renewal fees charged to practitioners under their supervision who are authorized to prescribe or dispense controlled substances by up to $10 annually, the proceeds of which would be ~~continuously appropriated to the Department of Justice,~~ *deposited into the CURES Fund* for support of CURES, as specified.

Vote: majority. Appropriation: ~~yes~~ *no*. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The Controlled Substance Utilization Review and Evaluation System (CURES) is a valuable investigative, preventive, and educational tool for law enforcement, regulatory boards, educational researchers, and the health care community. Recent budget cuts to the Attorney General's Division of Law Enforcement have resulted in insufficient funding to support the CURES Prescription Drug Monitoring Program (PDMP). The PDMP is necessary to ensure health care professionals have the necessary data to make informed treatment decisions and to allow law enforcement to investigate diversion of prescription drugs. Without a dedicated funding source, the CURES PDMP is not sustainable.

(b) Each year CURES responds to more than 60,000 requests from practitioners and pharmacists regarding all of the following:

(1) Helping identify and deter drug abuse and diversion of prescription drugs through accurate and rapid tracking of Schedule II, Schedule III, and Schedule IV controlled substances.

(2) Helping practitioners make better prescribing decisions.

(3) Helping reduce misuse, abuse, and trafficking of those drugs.

(c) Schedule II, Schedule III, and Schedule IV controlled substances have had deleterious effects on private and public interests, including the misuse, abuse, and trafficking in dangerous prescription medications resulting in injury and death. It is the intent of the Legislature to work with stakeholders to fully fund the operation of CURES which seeks to mitigate those deleterious effects, and which has proven to be a cost-effective tool to help reduce the misuse, abuse, and trafficking of those drugs.

SEC. 2. Section 805.8 is added to the Business and Professions Code, to read:

805.8. (a) If the Attorney General determines that the ability of regulatory agencies to adequately monitor prescribers and dispensers of Schedule II, Schedule III, and Schedule IV controlled substances has been compromised because insufficient funds exist to cover the operational costs of the Controlled Substance Utilization Review and Evaluation System (CURES) established by Section 11165 of the Health and Safety Code, or because a permanent and ongoing funding source sufficient to cover the operational costs of CURES has not been implemented by July 1, 2014, the Medical Board of California, the Dental Board of California, the *California* State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine~~,~~ shall increase the licensure, certification, and renewal fees charged to practitioners under their supervision who are authorized pursuant to Section 11150 of the Health and Safety Code to prescribe or dispense Schedule II, Schedule III, or Schedule IV controlled substances by up to ten dollars ($10) annually, but in no case shall the fee increase exceed the reasonable costs associated with maintaining CURES for the purpose of regulating prescribers and dispensers of controlled substances licensed or certificated by these boards.

(b) The funds collected pursuant to subdivision (a) shall be deposited in the CURES accounts, which are hereby created, within the Contingent Fund of the Medical Board of California, the State Dentistry Fund, the Pharmacy Board ~~Contingency~~ *Contingent* Fund, the Veterinary Medical Board Contingent Fund, the Board of Registered Nursing Fund, the ~~Contingent Fund of the~~ Osteopathic Medical Board of California *Contingent Fund*, the Optometry Fund, and the Board of Podiatric Medicine Fund. Moneys in the CURES accounts of each of those funds ~~are, notwithstanding Section 13340 of the Government Code, continuously appropriated without regard to fiscal year~~ *shall, upon appropriation by the Legislature, be available* to the Department of Justice solely for maintaining CURES for the purposes of regulating prescribers and dispensers of controlled substances. All moneys received by the Department of Justice pursuant to this section shall be deposited in the CURES Fund described in Section 11165 of the Health and Safety Code.

SEC. 3. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES accounts of the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Osteopathic Medical Board of California Contingent Fund, the Veterinary Medical Board ~~Contingency~~ *Contingent* Fund, the Optometry Fund, the Board of Podiatric Medicine Fund, and the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds for the Department of Justice. The department may seek and use grant funds to pay the costs incurred

from the reporting of controlled substance prescriptions to CURES. The department shall make information about the amount and the source of all private grant funds it receives for support of CURES available to the public. ~~Funds~~ *Grant funds* shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency, as described in this subdivision, shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal

controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) The CURES Fund is hereby established within the State Treasury. The CURES Fund shall consist of all funds made available to the Department of Justice for the purposes of funding CURES. Money in the CURES Fund ~~shall, notwithstanding Section 13340 of the Government Code, be continuously appropriated without regard to fiscal year~~ *shall, upon appropriation by the Legislature, be available for allocation* to the Department of Justice for the purposes of funding CURES.

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1. **Addition of Business and Professions Code Section 4008.5 – Requirement to Provide Arrest and Court Documents as Requested by the Board**

FOR DISCUSSION AND POSSIBLE ACTION:

Problem:
The board frequently has problems obtaining documents from some local or state agencies for the purpose of completing an applicant or licensee investigation; these agencies cite the board's lack of authority to receive these documents.

Proposed Solution:
Add section 4008.5 to provide the board with the explicit authority to receive certified records.

Draft language that could accomplish this is as follows:

4008.5 Access to Arrest and Conviction Records

Notwithstanding any other provision of law, the board may request a local or state agency to provide certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation. The local or state agency shall provide those records to the board upon receipt of such a request.

2. Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative

FOR DISCUSSION AND POSSIBLE ACTION:

Problem:
Pharmacy Law does not expressly state the experience earned must be in a facility licensed by the board.

Existing Law:
Section 4053 specifies the minimum requirements necessary to apply for a designated representative license. Subdivision (b)(2) requires the applicant to have one year of paid work experience, but does not specify the practice setting or facility in which this requirement must be satisfied.

Additional References:
Section 4022.5 defines a "designated representative."
Section 4053 authorizes the board to issue a license to a designated representative.

Proposed Solution:
Amend Section 4053 to clearly specify that the minimum of one year of paid work experience accepted by the board for an applicant for a designated representative license shall be earned in specified, licensed facilities.

Draft language that could accomplish this is as follows:

4053. Designated Representative to Supervise Wholesaler or Veterinary Food-Animal Drug Retailer

(a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development <u>certificate</u> equivalent.

(2) He or she shall have a minimum of one year of paid work experience <u>in a licensed pharmacy, drug wholesaler, drug distributor or drug manufacturer</u>, in the past three years, related to the distribution

or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

3. Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative

FOR DISCUSSION AND POSSIBLE ACTION:

Problem:
A pharmacy that is licensed by the board to compound sterile injectable drug products is not required to notify the board when it issues a recall notice for a sterile injectable drug product.

Proposed Solution:
Amend **section 4127.1** to require a pharmacy licensed by the board to provide the board within five (5) days any recall notice issued by the pharmacy for sterile injectable products.

Problem:
To provide for protection of the public, the board believes it is necessary to enhance the licensing and reporting requirements of nonresident pharmacies that are licensed by the board to compound sterile injectable drug products and who ship these products into or dispense these products to Californians. Requiring accreditation, as specified, will ensure the pharmacy has necessary standards and practices in place. Requiring the nonresident pharmacy to complete the board's Compounding Self-Assessment prior to licensure and prior to renewal will assist the pharmacy to ensure it is compliant with California's laws and regulations related to the compounding of drug products. Requiring the pharmacy to provide the board, within specified timeframes, recalls issued for sterile injectable drug products and disciplinary actions or suspension of accreditation will assist the board in the effective enforcement and application of Pharmacy Law.

Proposed Solution:
Amend **section 4127.2** to require a nonresident pharmacy seeking a license or renewing a license to compound sterile injectable drug products (1) hold current accreditation from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other private accreditation agency approved by the board; (2) provide the board with the most recent inspection report issued by the pharmacy's licensing agency; (3) provide the board with a copy of the self-assessment required by 16 CCR 1735.2 (i.e., "Compounding Self-Assessment); (4) require the nonresident pharmacy to notify the board within 30 days of disciplinary action taken by the resident state or suspension of accreditation; (5) require the nonresident pharmacy to notify the board within five (5) days any recall notice that the pharmacy issues for sterile injectable drug products that have been shipped to or dispensed in California; (6) remove licensure exemptions for nonresident pharmacies; and (7) strike the operative date.

Drafts that could accomplish this purpose are as follows:

4127.1. License to Compound Injectable Sterile Drug Products Required

(a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Public Health and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(f) A pharmacy that compounds sterile injectable products shall provide the board, within 5 days, any recall notice issued by the pharmacy for sterile injectable products.

(continued)

4127.2. Nonresident Pharmacy – License to Compound and Ship Injectable Drug Products into California Required

(a) A nonresident pharmacy may not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound sterile injectable ~~sterile~~ drug products may only be issued for a location that is licensed as a nonresident pharmacy. ~~Furthermore, the~~ The license to compound sterile injectable ~~sterile~~ drug products may only be issued to the owner of the nonresident pharmacy ~~license~~ licensed at that location provided it also holds current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agency approved by the board.

(c) A license to compound sterile injectable ~~sterile~~ drug products may not be issued or renewed until the board receives all of the following from the nonresident pharmacy:

(1) A copy of ~~an~~ the most recent inspection report issued by the pharmacy's licensing agency when available.

(2) ~~, or a~~ A report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

~~(2)~~ (3) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(4) A copy of the self-assessment form required by section 1735.2 of Title 16 of the California Code of Regulations.

(d) A nonresident pharmacy licensed pursuant to this section must provide the board, within 30 days of either disciplinary action taken by the resident state or suspension of accreditation.

(e) A nonresident pharmacy licensed pursuant to this section shall provide the board, within 5 days, any recall notice issued by the pharmacy for sterile injectable drug products that have been shipped or dispensed into California.

~~(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.~~

~~(d) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.~~

5. Other Legislative Proposals

SUBJECT: B&P Code Section 119 - Criminal Prosecution as Sole Remedy

Problem / Summary:
Current law only allows DCA regulatory agencies to pursue criminal misdemeanor filings for violations of B&P Code 119. Although individuals who commit these violations represent a risk to the public and legitimate licensees, workload considerations may prevent some district attorneys from pursuing criminal charges, especially if a consumer injury directly resulting from the B&P 119 violation can't readily be established. Consequently, individuals who have, in fact, violated the law may avoid having any record of their violations.

Solution:
Work with the department to amend Section 119 to provide the board with the express authority to issue administrative citations for violations that are not pursued criminally. This also will enable the board to establish a record of violations that can be made available for the public to use in making consumer choices.

A draft that could accomplish this purpose is as follows:

119. Any person who does any of the following is guilty of a misdemeanor and is, in addition, subject to disciplinary action in accordance with the provisions of this code:
(a) Displays or causes or permits to be displayed or has in his or her possession either of the following:
(1) A canceled, revoked, suspended, or fraudulently altered license.
(2) A fictitious license or any document simulating a license or purporting to be or have been issued as a license.
(b) Lends his or her license to any other person or knowingly permits the use thereof by another.
(c) Displays or represents any license not issued to him or her as being his or her license.
(d) Fails or refuses to surrender to the issuing authority upon its lawful written demand any license, registration, permit, or certificate which has been suspended, revoked, or canceled.
(e) Knowingly permits any unlawful use of a license issued to him or her.
(f) Photographs, photostats, duplicates, manufactures, or in any way reproduces any license or facsimile thereof in a manner that it could be mistaken for a valid license, or displays or has in his or her possession any such photograph, photostat, duplicate, reproduction, or facsimile unless authorized by this code.
(g) Buys or receives a fraudulent, forged, or counterfeited license knowing that it is fraudulent, forged, or counterfeited. For purposes of this subdivision, "fraudulent" means containing any misrepresentation of fact.
As used in this section, "license" includes "certificate," "permit," "authority," and "registration" or any other indicia giving authorization to engage in a business or profession regulated by this code or referred to in Section 1000, ~~or~~ 3600, or 4000.

SUBJECT: Implementing AB 377 (Solorio) – Clean-up

Purpose: AB 377 (Solorio) was signed by the Governor and goes into effect 1/1/2013. This bill created a new Article 7.6 in Chapter 9 of Division 2 of the Business and Professions Code. Section 4128 specifies requirements for a centralized hospital packaging pharmacy and further specifies that a hospital must obtain a specialty license from the board prior to engaging the functions so authorized.

Current Pharmacy Law (Section 4107) specifies that one site may possess only one site license, with few exceptions.

Proposed Change:
The amendment to 4107 is necessary to update Pharmacy Law to specify that in addition to holding a Hospital Pharmacy license from the board, the Hospital may also hold a specialty license to perform centralized packaging, as described in Section 4128.

A draft that could accomplish this purpose is as follows:

4107. (a) The board may not issue more than one site license to a single premises except as follows:

(1) To ~~to~~ issue a veterinary food-animal drug retailer license to a wholesaler pursuant to section 4196.

(2) To ~~or to~~ issue a license to compound sterile injectable drugs to a pharmacy pursuant to section 4127.1.

(3) To issue a centralized hospital packaging license pursuant to section 4128.

(b) For the purposes of this subdivision, "premises" means a location with its own address and an independent means of ingress and egress.